Health Protection and Food Laws

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Contents

Introduction

The purpose of this book – to explain the major aspects of the Food and Drugs Act and Regulations, with some reference to other related federal food legislation – has not changed since its first printing in 1971. However, much of the content and format has been revised. It is hoped this new edition will better serve as a reference for nutritionists, dietitians, home economists, public health officials, educators and members of the food industry.

The information in this book reflects the legislation, regulations and guidelines in effect as of October 1985. For current information, please contact your local Health Protection Branch office.

Chapter 1 presents an overview of the legislation both in regard to its scope in food safety and quality, and the influence of international activities. Chapter 2 deals with food labelling and advertising requirements while Chapter 3 discusses food standards and other compositional requirements. The 10 following chapters cover the regulations within specific areas such as food additives and microbial contaminants. The final chapter is new. It explains the organization of the Health Protection Branch of Health and Welfare Canada.

The Health Protection Branch, in fulfilling its responsibilities to administer the Food and Drugs Act and Regulations, performs many regulatory activities with regard to food quality and safety. These include:

- research, data collection, analysis of health effects, products and industry conditions to identify the extent of a hazard;
- evaluation of product submissions, and assessment of products and processes for compliance with regulations;
- education of health professionals, educators and consumers to promote safe use and education of industry to encourage voluntary compliance.

Health Protection Branch
December 1986

Chapter 1

Food Legislation: An Overview

The Food and Drugs Act

The federal *Food and Drugs Act* is designed to protect Canadians against health hazards and fraud from the sale of foods, drugs, cosmetics and medical devices, whether these items are products of Canada or imported.

Although the present *Act* was passed in 1953, it had its beginnings in the last century when it became apparent that adulterated liquor was a health hazard. The *Inland Revenue Act* of 1875 was the earliest Canadian law to protect the public against the adulteration of drinks, foods and drugs. Amended in 1884, it became known as the *Adulteration Act*. With the establishment of the Health Department and its Food and Drug Division in Ottawa in 1919, the *Adulteration Act* was repealed and superseded by the 1920 *Food and Drugs Act*. This was amended several times prior to the 1953 version still in force.

The Health Protection Branch of Health and Welfare Canada is responsible for the administration of health and safety provisions of the *Act*. These matters are considered to come within federal jurisdiction under the criminal law power of the Constitution. Sections 4, 5 and 7, reproduced below, are the principal sections of the Act dealing with food safety and quality, and economic fraud.

Section 4.
No person shall sell an article of food that
(a) has in or upon it any poisonous or harmful substance;
(b) is unfit for human consumption;
(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
(d) is adulterated; or
(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Section 5.
(1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.
(2) An article of food that is not labelled or packaged as required by the regulations, or is labelled or packaged contrary to the regulations, shall be deemed to be labelled or packaged contrary to subsection (1)...

Section 7.
No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions.

In addition, Section 3 of the *Act* deals with the prevention of claims directed at the general public for the cure of serious diseases, disorders or abnormal physical states (listed in Schedule A) which should be diagnosed and treated by a medical practitioner.

Section 3.
(1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A.
(2) No person shall sell any food, drug, cosmetic or device
    (a) that is represented by label, or
    (b) that he advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A.

Schedule A

Alcoholism
Alopecia
Anxiety state
Appendicitis
Arteriosclerosis
Arthritis
Bladder disease
Cancer
Convulsions
Depression
Diabetes
Disease of the prostate
Disorder of menstrual flow
Dysentery
Edematous state
Epilepsy
Gall bladder disease
Gangrene
Glaucoma
Gout
Heart disease
Hernia
Hypertension
Hypotension
Impetigo
Influenza
Kidney disease
Leukemia
Liver disease
Nausea and vomiting of pregnancy
Obesity
Pleurisy
Pneumonia
Poliomyelitis
Rheumatic fever
Scabies
Septicemia
Sexual impotence
Tetanus
Thrombotic and embolic disorders
Thyroid disease
Tuberculosis
Tumor
Ulcer of the gastro-intestinal tract
Vaginitis
Venereal disease

The Food Regulations

To keep up with new scientific or technological findings and to cope with the demands of a modern food industry, the legislation was designed to be flexible enough to allow for the introduction of new regulations without undue delay. Section 25 of the *Food and Drugs Act* gives authority to the Governor in Council to make new regulations or amend existing ones, as made necessary, for example, by changing technology or the discovery of new hazards.

These regulations have the same force and effect as the *Act* itself. Under the regulation-making authority, it is possible to promulgate regulations that will control the use of food additives or the fortification of foods with nutrients in the interest of preventing injury to the health of the consumer or preventing deception. It is also possible to establish regulations declaring foods to be adulterated if any prescribed substance is present therein. Hence foods containing pesticide residues higher than the levels specified by the *Regulations* are considered to be adulterated. Standards of purity, potency and quality may be promulgated, and as a result, microbiological levels have been established for foods as necessary.

Regulations are constantly reviewed, developed and amended. The stimulus for change may arise from several sources, including consumer groups, food industry submissions and research findings. Studies

are conducted in Health Protection Branch laboratories and by university and industry scientists and food technologists to test, for example, the toxicity of food additives or agricultural chemicals, to study the safety of new processing techniques, or to examine the nutritional status of a population.

Prior to recommending a new regulation or an amendment to an existing one, an extensive consultative process is initiated. Key components in this process are the semi-annual publication of a Regulatory Agenda and the publication of Health Protection Branch *Information Letters*, both of which are complemented by other informal consultative mechanisms.

The Regulatory Agenda

In May and November of each year, the Government publishes the regulatory agendas of 10 federal departments and four federal agencies in Part I of the *Canada Gazette*. For the Health Protection Branch, this provides an early notice of proposed or contemplated regulatory initiatives, research interests and changes in matters of food policy, to inform business, labour and consumers of regulatory activities that may affect them. It does not provide detailed information on any particular initiative, but rather gives readers enough information to decide whether they wish to learn more or to become involved in the consultative process. Each entry in the Agenda lists a "Contact Person" who can provide more specific information. In addition, each entry gives a timetable for possible action.

Information Letters

In 1948, with the issuance of the first "Trade Information Letter", an important initiative was begun to inform the trade and other interested parties of proposed regulatory changes. When contemplating a major regulatory change, the Health Protection Branch publishes an *Information Letter* outlining the problem and the philosophy of the proposed regulation, and soliciting comments on the intended changes. The *Letter* is given wide distribution to the food industry, health professionals, consumer groups and other interested parties. An interval of 60 to 90 days is the usual time period for comments, but for particularly complex proposals the period may be longer. The Branch then publishes a second *Information Letter* summarizing the comments received and stating its final regulatory position, and the reasons for its decisions.

The Regulatory Process

After a decision has been made on the content of proposed regulations, the Branch provides the principles and details of the proposals to the departmental Legal Services, who then draft them in regulation form.

Following a review by the Department of Justice and senior management, the regulation is recommended to the Minister of National Health and Welfare, for presentation to the Governor in Council (a committee of Cabinet). If passed by this order-in-council process, it acquires the power of law through proclamation in Part II of the *Canada Gazette*.

Socioeconomic Impact Analysis

The Health Protection Branch is required by the Government's Socioeconomic Impact Analysis policy (SEIA) to prepare socioeconomic impact studies for any major new regulations or amendments to regulations, when these pertain to health, safety or fairness in the market place. "Major" regulations are considered to be those that would impose costs on the regulated industries and government combined, in excess of either $10 million in any one year or $3.5 million a year, over a period of years. In conducting an SEIA, the Branch is required to consult with parties who are directly affected, estimate the costs and benefits of the proposed regulations, compare alternatives and consider other impacts such as who gains and who loses.

A summary of the complete SEIA must be published in Part I of the *Canada Gazette* at least 60 days before promulgation of the regulation. The entire analysis must be publicly available and the Branch must respond to comments. In addition to formal SEIA studies involving major regulations, all other proposed regulations are screened for their potential cost to society prior to promulgation.

The purpose of the SEIA policy is to promote a more thorough and systematic analysis of the impact of new regulations, and to provide an opportunity for increased public participation in the regulation-making process.

The Branch has maintained excellent relations with the food industry, and consumer and professional organizations throughout the years, and proposals from these groups are carefully considered. By means of various formal and informal consultative procedures, the Health Protection Branch ensures that the widest possible audience is informed of any proposed changes to the regulations.

Framework for Safety Decisions

When assessing whether changes to existing regulations may be needed or if the introduction of new regulations is required, the ultimate objective is to ensure that the food supply is without appreciable risk, and is of appropriate nutritional quality.

Several criteria, based on internationally recognized principles, are used in making safety decisions. Although it is difficult to isolate any one factor in influencing the health of the population, certain indicators of the effectiveness of the entire program are available through statistical information and expert opinion. For example, Canadian morbidity

and mortality statistics compare favourably with those of other developed countries. Although this can not be entirely attributed to intervention strategies, failure to take such action may adversely affect such statistics.

As a final step in the safety evaluation process, intervention options are reviewed. In certain cases products or substances may be banned. Less stringent but effective control may also be attained by limiting the concentration or residue permitted or by limiting the products to which a substance may be added or by imposing marketing restrictions or label warnings. Finally, an education program may be all that is needed to protect the consumer.

Other Departments and Food Legislation

Health and Welfare Canada is one of several federal government departments involved with food. The Department of Consumer and Corporate Affairs is responsible for enforcing the economic fraud and labelling aspects of the *Food and Drugs Act and Regulations*. Section 5 of the *Act* is primarily its responsibility, although the nutritional quality and safety aspects of that section fall mainly to Health and Welfare. The *Consumer Packaging and Labelling Act and Regulations* is also administered by Consumer and Corporate Affairs and has general requirements for the packaging, labelling, sale, importation and advertising of a wide range of prepackaged products, including foods.

Agriculture Canada is responsible for the *Canada Agricultural Products Standards Act* (CAPS), an umbrella statute for standardizing and grading agricultural products and regulating international and interprovincial trade in these products. Under this *Act*, such regulations as the *Processed Fruit and Vegetable Regulations* and the *Dairy Product Regulations* govern plant sanitary conditions and registration, and grades, standards and labelling for designated processed fruit and vegetable and dairy products. Agriculture Canada administers the CAPS *Act* and *Regulations* at all production levels, whereas Consumer and Corporate Affairs administers them at the retail level.

Agriculture Canada's responsibilities also include the federal *Meat Inspection Act*, which requires the inspection of meat and meat products entering interprovincial and international trade. This *Act* and its *Regulations* deal with the registration of establishments, sanitation, standards, labelling, packaging and marking.

The Department of Fisheries and Oceans is responsible for the quality of domestic and imported fish and shellfish and for seeing that they are produced under sanitary conditions, and properly packaged and labelled. This is accomplished through application of the *Fish Inspection Act and Regulations* and relevant requirements of the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act*.

Interdepartmental cooperation is used to reduce regulatory burden and costs. As an example, Agriculture Canada's meat inspectors monitor compliance with the *Food and Drug Regulations* in all establishments, registered under the *Meat Inspection Act*, and the same department gives prior approval to labels and formulations of meat products made in these establishments.

International Program

Canada is one of 120 member nations currently participating in the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Food Standards Programme administered by the Codex Alimentarius Commission in Rome. The two basic goals of this program are to protect the health of consumers on a global level and to reduce or eliminate such barriers to trade as differences in food compositional standards, labelling differences and differing provisions for the use of food additives.

Canada is the host country for two of the 26 subsidiary bodies making up the Codex Alimentarius Commission: The Codex Committee on Food Labelling and the Codex Committee on Vegetable Proteins. Some of the other committees have developed international standards for such products as fruit juices, fats and oils, and processed fruits and vegetables. Other committees deal with issues crossing commodity lines such as the Food Additive Committee, the Food Hygiene Committee and the Committee on Pesticide Residues. The federal departments involved in food regulations maintain a continuing review of Codex standards and codes of practice. Many commodity standards found in Canadian regulations, as well as the maximum limits for pesticide residues, reflect the influence of the international deliberations.

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The Food and Drugs Act and Regulations may be purchased from:

The Canadian Government Publishing Centre
Supply and Services Canada
Ottawa, Canada
K1A 0S9

Health Protection Branch Information Letters available from:

Administrative Services
2nd floor west, Sir Frederick Banting Bldg.
Tunney's Pasture, Ottawa
K1A 0L2

Material available from the Field Operations Directorate, Health Protection Branch:

Inspection for Health Protection (leaflet).
Protection is Our Middle Name (folder).
Code of Practice: General Principles of Food Hygiene for Use by the Food Industry in Canada (1983) (booklet).

Chapter 2

Food Labelling, Advertising and Claims

To protect the consumer from being misled about the characteristics of food products, and to assist in the wise and knowledgeable purchase of foods, a detailed set of regulations and guidelines on labelling, advertising and claims has evolved.

The Department of Consumer and Corporate Affairs administers the labelling, packaging and advertising requirements of the *Consumer Packaging and Labelling Act and Regulations* and the *Food and Drugs Act and Regulations*. The Health Protection Branch provides advice to Consumer and Corporate Affairs on labelling and advertising matters relating to health. The main features of these labelling regulations are outlined here. Further details may be obtained from Consumer and Corporate Affairs Canada.

Basic Labelling Information Required

- the common name of the food;
- the net quantity of the food;
- the name and address of the person responsible for the product;
- the list of ingredients;
- the durable life date and storage instructions as required.

All mandatory information must appear in both French and English, with the exception that the name and address of the manufacturer may appear in either language.

Common Name

The common name is the name of the food in boldface type or otherwise prescribed in the *Food and Drug Regulations*, or in the absence of either of the foregoing, the name by which it is commonly known.

Net Quantity

Prepackaged products, with certain specified exceptions must carry a declaration of the net quantity by volume for liquid or viscous products and by weight for solid products. These must be in metric units.

Food products exempted from a net quantity declaration are:

- prepackaged individual servings prepared by a commissary and sold from vending machines or mobile canteens;
- prepackaged one-bite confections sold individually;
- prepackaged individual portions of food served by restaurants with meals or snacks;
- prepackaged fresh fruits or vegetables packaged in a wrapper or confining band of less than ½ inch width;
- prepackaged raspberries or strawberries that are packaged in the field in containers having a capacity of 1.14 litres or less.

Name and Address of Person Held Responsible for the Product

The name and address of the person held responsible for the product is defined as the identity and principal place of business of the person by or for whom the food was manufactured or produced for resale. It can be the name of the actual manufacturer of a product or the name of a firm or store having had the product manufactured under its own brand name.

List of Ingredients

Food products, with some exceptions, must carry a list of ingredients in descending order of proportion or as a percentage of the prepackaged product.

The exceptions are as follows:

- prepackaged products packaged from bulk on the retail premises;
- prepackaged individual portions of food served by restaurants with meals and snacks;
- individual portions of food prepared by a commissary and sold from a vending machine or mobile canteen;
- prepackaged meat or poultry products that are barbecued, roasted or broiled on the retail premises;
- standardized alcoholic beverages;
- vinegars.

The following ingredients may be listed in any order immediately after the other ingredients:

- spices, seasonings and herbs, except salt;
- natural and artificial flavours;
- flavour enhancers;
- food additives;
- vitamins;
- salts or derivatives of vitamins;

- mineral nutrients;
- salts of mineral nutrients.

Ingredients must be listed under their common name, with the exception that the following ingredients may be listed under a class name.

Ingredient	*Class name*
Vegetable fats or oils, except cocoa-butter, coconut oil, palm oil or palm kernel oil	"vegetable oil" or "vegetable fat"
Marine fats or oils	"marine oil"
Permitted food colours	"colour"
Natural flavour	"flavour"
Artificial flavours	"artificial flavour" "imitation flavour" or "simulated flavour"
Spices, seasonings or herbs, except salt	"spices" "seasonings" or "herbs"
Any combination of all types of milk: whole, skimmed or partly skimmed, cream, butter and butter oil	"milk solids" or "dairy products"
Any combination of disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetra sodium pyrophosphate and sodium acid pyrophosphate	"sodium phosphate" or "sodium phosphates"

Meat, poultry, fish or their byproducts must be identified under their individual names. In the case of plant protein products, the name of the source of the protein must be given.

For optional ingredients or those that may be substituted for others in the preparation of a product, the label may indicate all of the ingredients that are likely to be used in the product during one year. However, there must be a clear indication that these specific ingredients may not all be present in a given package of the food.

Ingredients containing more than one component require complete component listing unless exempted by the regulations. Examples of ingredients for which a declaration of components is not required are butter, flour and cheese.

Durable Life Date

The label of foods which have a durable life of not more than 90 days must carry a durable life date.

"Durable life" is defined as the period of time, beginning on the day on which the prepackaged product is packaged for retail sale, during which a product stored under proper conditions will retain, without appreciable deterioration, its normal wholesomeness, palatability and nutritional value.

The date on which a product may no longer meet all these conditions is referred to as the durable life date and is indicated on the label as "Best before *(a given date)*." In the case of meat, fish and poultry, the packaging date must also be shown.

It should be noted that products may still be safe to eat after the durable life date, but the consumer may expect some deterioration in quality. An exception in this regard is the date appearing on infant formulas which is the true "expiration date" after which the manufacturer does not recommend that the product be consumed.

The following foods are exempted from a durable life date:

- prepackaged fresh fruits and vegetables;
- prepackaged individual portions of food served by restaurants with meals and snacks;
- individual portions of food prepared by a commissary and sold from a vending machine or mobile canteen;
- prepackaged fresh or previously frozen meat, poultry or fish or their byproducts;
- prepackaged donuts.

Artificial Flavours

When an artificial flavour is used in a product and the label illustrates the natural product this flavouring imitates, it should be clearly indicated near the "vignette" or central label design, or close to the common name of the product, that the flavouring is an imitation, artificial or simulated.

Nutrition Labelling

The *Food and Drug Regulations* permit the declaration of the energy value of a food and the content of protein, fat, carbohydrate, sodium and potassium.

The information must be given per 100 grams (g) or 100 millilitres (mL) of the food but may also be given for any stated quantity. The energy value, carbohydrate and fat content may be declared by themselves but if the amount of protein is given, the fat and carbohydrate content must also be declared. Similarly, the declaration of the sodium content must be accompanied by a statement of the potassium content and vice versa.

The quantities of naturally-occurring vitamins and minerals in a food may be declared except in certain substances (e.g. foods for children under the age of two years; sole sources of nourishments). The quantities of added vitamins and minerals present in a food must be declared per 100 g or per 100 mL of the food.

Advertising

As with labelling, regulations and guidelines on advertising have evolved over time to protect the public interest. In some cases,

advertisements must be "precleared" before being shown.

For example, all advertisements on Canadian television and radio making claims about foods must be cleared through the Canadian Radio-television and Telecommunications Commission and are submitted to the Department of Consumer and Corporate Affairs for review.

Although preclearance is not required for print advertising, officers of the Department of Consumer and Corporate Affairs regularly conduct surveillance of food advertising appearing in newspapers and magazines published in Canada for false or misleading information. The label or any other written material accompanying a product to be sold is also considered to be advertising and is subject to control under the *Food and Drugs Act*. On the other hand, false or misleading information published in books or magazines cannot be controlled if it is not directly associated with the promotion of a product.

Claims

In addition to the mandatory information that must appear on labels, manufacturers may wish to state additional information about their products, either on the label or in advertising. Guidelines have been developed for the types of claims that may legitimately be made for foods to prevent the consumer from being misled.

Food and Disease

Claims that foods may be useful in the cure and treatment of disease are not permitted.

Food and Energy

For the purposes of labelling, advertising and claims, energy means a food's energy value expressed in calories or kilojoules and refers to the energy made available to the body when a food's protein, fat, carbohydrate, alcohol and/or other constituents are metabolized.

Protein

Claims for protein on the label or in advertising may be made only for products which are good or excellent sources of that nutrient. No other mention of protein may be made except in a statement of the amount of protein, fat and carbohydrate, in a food, or in the common name of an ingredient such as hydrolyzed vegetable protein.

"Excellent" or "Good" source of protein: A food may be represented as an "excellent" or a "good" dietary source of protein if it meets the criteria defined in the *Food and Drug Regulations* for these claims. The phrase "An excellent (dietary) source of protein" may be used if the protein rating is not less than 40, or 20 for a food prepared especially for infants. The phrase "A good (dietary) source of protein" may be used if the protein rating of that food is not less than 20.

Protein rating: Protein rating is a means to estimate the nutritional value of protein sources as part of the diet. It is used to judge the validity of claims for labelling and advertising purposes and to define the nutritional quality of proteins in substitute foods, but is not intended to be used in the evaluation of diets.

Two factors are considered in determining the protein rating of a food:

- the quality of the protein as determined by the protein efficiency ratio (P.E.R.). This method of protein evaluation is defined as the weight gain in grams of a growing rat divided by the grams of protein consumed in a standard four-week assay.
- the quantity of protein provided by a Reasonable Daily Intake (R.D.I.) of that food. R.D.I. is an estimate of the probable daily intake of a food in the Canadian diet, based on usual food consumption patterns. These are set out in Schedule K, Part D of the *Regulations*.

These factors are summarized in the following formula: P.E.R. x grams of protein in R.D.I. = Protein Rating.

For example, since the P.E.R. of egg protein is 3.8 and an R.D.I. of eggs (2 eggs or 100 g) will provide 12.8 g of protein, the protein rating for eggs is 3.8 x 12.8 = 48.6. Eggs may thus be claimed to be an excellent source of protein because their rating is above 40.

A food with a rating below 20 does not contribute significant amounts of protein to the diet, and it is considered misleading to attach

Table 1: Protein Rating of Certain Foods

Food	*R.D.I. grams*	*Protein in R.D.I. grams*	*P.E.R.*	*Protein rating*
Cabbage	100	1.4	0.9	1.3
Whole wheat	30	3.0	1.5	4.5
Rolled oats	30	3.8	2.1	8.0
Rolled oats plus milk (1:4)	150	8.0	3.2	25.6
"Protein" cereal	30	6.8	0.03	0.2
"Protein" cereal plus milk (1:4)	150	10.0	2.0	20.0
White bread	150	12.6	1.0	12.6
Whole-wheat bread	150	15.5	1.1	17.1
"Protein" bread	150	17.1	1.3	23.0
Soybeans (dry)	30	10.5	2.3	24.1
Cheese	60	18.6	2.3	43.2
Whole egg	100	12.8	3.8	48.6
Beef	100	21.0	3.2	67.2
Whole milk	900	32.0	2.8	89.5

any special significance to its protein content, or to use it in any way as the basis of advertising claims.

Claims regarding the functions of protein: If the food is described on the label as an "excellent" or "good" source of protein, claims may be made that proteins help children grow, or that proteins are needed for the renewal and maintenance of body tissues (see Table 1).

Claims for foods containing added vitamins or minerals

The label of a food to which vitamins or minerals have been added must carry a statement of the quantity of the added nutrient present in the food. Claims may also be made that the food contains the added nutrient (see Tables 2 and 3).

Claims for foods intended for children

Where a food to which no vitamin or mineral nutrient has been added is intended solely for children under two years of age, a declaration of the quantity of the vitamin or mineral may be made on the label if a reasonable daily intake of the food will provide the following minimum amount of the specified nutrient:

vitamin A	600 I.U.
thiamine	0.25 mg
riboflavin	0.4 mg
niacin	2.5 mg
ascorbic acid	7.5 mg
pyridoxine	0.25 mg
calcium	150 mg
phosphorus	150 mg
iodine	0.05 mg
iron	2 mg

Table 2: Permitted Vitamin and Mineral Claims

	Minimum of R.D.I. for "excellent source"	*Minimum of R.D.I. for "good source"*
Vitamin		
Vitamin D (I.U.)	300	
Vitamin A (I.U.)	1200	600
Thiamine (mg)	0.45	0.25
Riboflavin (mg)	0.75	0.4
Niacin (mg)	4.5	2.5
Vitamin C (mg)	15	7.5
Mineral		
Calcium (mg)	300	150
Phosphorus (mg)	300	150
Iron (mg)	4	2

Table 3: Specific Vitamin and Mineral Claims

	Minimum of R.D.I. for "Excellent Source"	*Specific claim*
Vitamin		
Vitamin D (I.U.)	300	Factor in the normal development and maintenance of bones and teeth, especially in infancy and childhood. Factor in the maintenance of good health
Vitamin A (I.U.)	1200	Factor in the maintenance of good health
Thiamine (mg)	0.45	Factor in the maintenance of good health
Riboflavin (mg)	0.75	Factor in the maintenance of good health
Niacin (mg)	4.5	Factor in the maintenance of good health
Vitamin C (mg)	15.0	Factor in the normal development and maintenance of bones, cartilage, teeth and gums
Mineral		
Calcium (mg)	300	Factor in the normal development and maintenance of bones and teeth, especially in infancy and childhood. Factor in the maintenance of good health
Phosphorus (mg)	300	Factor in the normal development and maintenance of bones and teeth, especially in infancy and childhood. Factor in the maintenance of good health
Iron (mg)	4	Factor in the prevention of iron deficiency Factor in the maintenance of good health

Fatty Acids and Cholesterol

No statements or claims may be made for the cholesterol or fatty acid content of a food with the following exceptions:

(1) B.09.021. Where the proportion of cis-methylene interrupted polyunsaturated fatty acids contained in the total fat is at least 40 per cent in the case of an oil and at least 25 per cent in the case of shortening, margarine or a margarine-like product, and the proportion of saturated fatty acids does not exceed 25 per cent in either case, a person may, in an advertisement or on the label of such product, state:

(a) the percentage of saturated fatty acids, on a total fat basis; and

(b) the percentage of polyunsaturated fatty acids on a total fat basis, where it is calculated as total cis-methylene interrupted polyunsaturated fatty acids, if those statements are grouped together and given equal prominence in the advertisement or on the label.

(2) Labels of special dietary foods represented for use in fat-modified diets must carry the following information:
    (a) cholesterol content expressed in milligrams
    (b) in the case of "fat-modified" foods, the content of linoleic acid, saturated fatty acids and the sum of saturated plus trans fatty acids expressed as a percentage of the total fat.

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Health Protection Branch Information Letters available from:
Administrative Services
2nd floor west
Sir Frederick Banting Building
Tunney's Pasture
Ottawa
K1A 0L2

The Food and Drugs Act and Regulations may be purchased from:
Canadian Government Publishing Centre
Supply and Services Canada
Ottawa, Canada
K1A 0S9

Material available from the Food Directorate, Health Protection Branch
Infant feeding – Dispatch No. 46

Chapter 3

Food Standards and Other Compositional Requirements for Foods

The *Food and Drug Regulations* contain standards of identity or composition for approximately 300 food items. The early development of standards was necessary to provide criteria by which adulteration could be determined. Over time, they were increasingly used to define permitted ingredients and other compositional aspects of foods to meet consumer expectations. Because the Health Protection Branch has worked closely with the food industry to develop these standards, there is a high degree of voluntary compliance.

The Branch is also strongly committed to the international food standardization program, referred to in Chapter 1, and has amended standards, where appropriate, to bring Canadian requirements into conformity with those existing internationally.

Food Standards

The following two examples of food standards indicate the identity type and compositional type.

Identity Type

B20.002 (S). Black Tea shall be black tea or a blend of two or more black teas and shall contain, on the dry basis, not less than 30 per cent water-soluble extractive, as determined by official method FO-37, Determination of Water-Soluble Extractive in Tea, October 15, 1981, and not less than four per cent and not more than seven per cent total ash.

Compositional Type

This type of standard may list mandatory or permitted ingredients or indicate analytical requirements which must be met, e.g., B.07.040 (S) Mayonnaise, Mayonnaise Dressing or Mayonnaise Salad Dressing

(a) shall be a combination of
    (i) vegetable oil
    (ii) whole egg or egg yolk, in liquid, frozen or dried form, and
    (iii) vinegar or lemon juice
(b) may contain
    (i) water
    (ii) salt
    (iii) a sweetening agent
    (iv) spice or other seasoning except turmeric or saffron
    (v) citric, tartaric or lactic acid, and
    (vi) a sequestering agent; and
(c) shall contain not less than 65 per cent vegetable oil.

Nutritional Requirements

Besides defining compositional requirements based on traditional expectations, increasing attention has been paid to nutritional aspects of both standardized and unstandardized foods. In an endeavour to prevent the Vitamin D deficiency disease rickets, which, even until fairly recently, was manifest in Canada, the standards for fluid milk were amended to require fortification with Vitamin D. Enrichment of white flour was made mandatory to restore the significant B vitamins and iron lost in processing. The standards for a variety of prepared meat products including sausages and luncheon meat were amended to establish minimum protein contents when, as a result of modern technology, it became apparent that stable meat emulsions could be made with increasingly lower protein contents.

The Status of Food Standards

The federal authority to enact national food composition standards was called into serious question by the 1979 Supreme Court decision in the Labatt's "Lite Beer" case. The Supreme Court found that the prescribing of compositional standards for malt liquor products was "ultra vires" or beyond the power of Parliament, based on the criminal law powers constitutionally granted to the federal government. Since the *Food and Drugs Act* as currently constructed is based on the criminal law authority, this decision has placed in jeopardy all food standards found in the *Food and Drug Regulations* that merely serve to identify or characterize the product, even though the Court's decision was restricted to the compositional standards for beer, ale and related products. In order to rectify the situation, appropriate legislative amendments are being examined to clarify the status of food standards.

Compositional Requirements for Unstandardized Foods

In recent years there has been a trend to the development of "performance" criteria for foods, particularly when the objective has been one of

establishing minimum nutritional requirements rather than the strict delineation of permitted ingredients. Examples of where this has taken place are as follows.

Substitutes for Traditional Foods

Substitutes for staple foods are becoming more popular and consumption of some of these products might lead to health concerns if they do not provide adequate nutritional value. There are no general regulations controlling the introduction of substitute foods to the market and each case is treated separately. The Health Protection Branch has guidelines for the addition of nutrients to such foods, described under Chapter 4 "Enrichment of Foods."

A substitute food designed to replace a staple food in the diet should have a nutritional value similar to that of the food it is intended to replace. Where necessary, regulations are promulgated specifying the levels of nutrients that must be present in the substitute food and, if applicable, the protein quality requirements.

The name of a substitute food is also subject to regulation as it must be clearly differentiated from the food it replaces in order to avoid confusion.

Examples of substitute foods are simulated meat products. Protein and fat requirements are set out in Table 4.

Table 4: Protein and Fat Requirements for Meat Substitutes and Extenders

		Minimum protein		*Maximum fat*
		%	*Rating*	%
Extender for meat*		16	40	
Meat	meat + extender	16		25
	meat + filler + extender	13		25
	simulated meat*	16	40	25
Ground meat	ground meat + extender (lean)	16		17
	ground meat + extender (medium)	16		23
	ground meat + extender (regular)	16		30
	simulated ground meat (lean)*	16	40	17
	simulated ground meat (medium)*	16	40	23
	simulated ground meat (regular)*	16	40	30
Sausages	fresh meat + extender	9		40
	simulated fresh*	9	23	40
	cooked + extender	11		25
	simulated cooked*	11	28	25
Potted meat and meat paste	meat + extender	9		30
	simulated product*	9	23	30
Bacon	simulated side bacon*	25	20	

* Essential amino acids can be added to these products in amounts only sufficient to improve the nutritional quality of the protein.

Meat substitutes and extenders must also meet the vitamin and mineral requirements shown in Table 5.

Table 5

Nutrient	*Minimum amount per gram of protein*
Copper	4.4 ug
Folic acid	0.45 ug
Iron	0.25 mg
Magnesium	1.1 mg
Niacin	0.34 mg
Pantothenic Acid	0.04 mg
Potassium	20 mg
Pyridoxine	0.02 mg
Riboflavin	0.01 mg
Thiamine	0.02 mg
Vitamin B_{12}	0.08 ug
Zinc	0.20 mg

Simulated whole egg products are a further example of substitute foods. The following *Regulation* applies to their composition.

B22.032, "No person shall sell any product simulating whole egg unless the product

(a) is made from liquid, dried or frozen egg albumen or mixtures thereof;

(b) has a protein rating of not less than 40 as determined by the official method;

(c) notwithstanding sections D.01.009 and D.02.009, contains, per 100 grams on a ready to use basis,

(i) not less than

(A) 50 mg calcium
(B) 2.3 mg iron
(C) 1.5 mg zinc
(D) 130 mg potassium
(E) 1000 I.U. vitamin A
(F) 0.10 mg thiamine
(G) 0.30 mg riboflavin
(H) 3.60 mg niacin
(I) 1.60 mg pantothenic acid
(J) 0.20 mg vitamin B6
(K) 0.50 mcg vitamin B12
(L) 0.02 mg folic acid
(M) 2 I.U. alpha-tocopherol, and

(ii) not more than 3 mg cholesterol

(d) has a calcium to phosphorus ratio of not less than one part calcium to four parts phosphorus;

(e) contains in the total fat of any fat or oil used not less than 40 per cent cis-cis methylene interrupted polyunsaturated fatty acids and not more than 20 per cent saturated fatty acids."

Foods Used as Sole Source of Nourishment

Infant formulas, meal replacements and formulated liquid diets are foods which may be used as sole sources of nourishment. These foods

Table 6: Composition per 100 Available Kilocalories of Infant Formula

	Minimum	*Maximum*
Fat	3.3 g	6 g
Linoleic acid	500 mg	
C22 monoenoic fatty acid		1 cal
Protein*	1.8 g	4 g
Biotin	2 mcg	
Folic acid	4 mcg	
Niacin	250 mcg	
D-pantothenic acid	300 mcg	
Riboflavin	60 mcg	
Thiamine	40 mcg	
Alpha-tocopherol	0.6 I.U.	
Vitamin A	250 I.U.	500 I.U.
Vitamin B_6	35 mcg	
Vitamin B_{12}	0.15 mcg	
Vitamin C	8 mg	
Vitamin D_1	40 I.U.	80 I.U.
Vitamin K	8 mcg	
Calcium	50 mg	
Chloride	55 mg	150 mg
Copper	60 mcg	
Iodine	5 mcg	
Iron	0.15 mg	
Magnesium	6 mg	
Manganese	5 mcg	
Phosphorus	25 mg	
Potassium	80 mg	200 mg
Sodium	20 mg	60 mg
Zinc	0.5 mg	
Choline	12 mg	

* Protein Quality is defined as being not less than 1.8 grams of nutritional quality equivalent to casein; or such an amount and quality of protein that, when the quality of the protein is expressed as a fraction of the quality of casein (a) the fraction will not be less than 85/100, and (b) the product obtained by multiplying the fraction by the gram weight of the protein will not be less than 1.8.

should be nutritionally complete and balanced insofar as science and technology permit. Regulations for these products include requirements for energy and both macro and micro- nutrients. For example, the *Regulation* for infant formula states:

B.25.052 "... no person shall sell or advertise for sale infant formula unless that food contains as normally consumed, (a) per 100 available kilocalories (see Table 6) and (b) a ratio of:

- Alpha-tocopherol to linoleic acid: not less than 0.6 International Units to one gram;
- calcium to phosphorus: not less than 1.2 grams to one gram and not more than 2.0 grams to one gram;
- Vitamin B_6 to protein: not less than 15 micrograms to one gram."

Meal replacements are single foods sold or advertised for sale as replacements for one or more daily meals and usually sold or represented for use in weight reduction diets.

Formulated liquid diets are sold for oral or tube feeding and are designed to be nutritionally complete. Nutritional requirements are described under Chapter 5 "Foods for Special Dietary Use."

Food Methodology

The *Food and Drug Regulations* make reference to two types of methodology – official and acceptable methods. "Official method" is defined in Section A.01.010 (h) of the *Food and Drug Regulations* as a method of analysis or examination designated as such by the Director for use in the administration of the *Act* and these *Regulations*. Official methods are specified by code, title and date in the regulation, e.g. FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981 (B.14.015). By definition, the official method is the only one used to determine compliance with a given regulation.

"Acceptable method" is defined as a method of analysis or examination indicated by the Director as acceptable for use in the administration of the *Act*. It is often a method that has been developed outside the Health Protection Branch by industry and is judged by the Branch to be acceptable for the intended purpose. For example, a sugar-free food is a carbohydrate-reduced food that, when ready to serve, (a) contains not more than 0.25 per cent available carbohydrate as determined by an acceptable method (B.24.005).

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Chapter 4

Enrichment of Foods

Approximately 35 years ago, regulations were developed to permit the addition of vitamins and other nutrients to certain standardized food products on the basis that consumers would benefit from such addition, and the foods in question were suitable carriers for the nutrient or nutrients. By the early 1950s, provision existed for the optional addition of Vitamin D to various fluid, evaporated and powdered milk products, for the addition of Vitamin C to apple juice, and for the addition of thiamine, niacin, riboflavin, iron and bonemeal to enriched flour.

Although the regulations were specific as applied to standardized foods, they essentially did not deal with unstandardized foods including beverages of many sorts, confections and others. During the 1950s and early '60s, there was increased commercial interest in the addition of vitamins to a wide range of foods, and it reached the stage where not only was there no nutritional justification for much of this addition, but there was mounting concern amongst medical practitioners and nutritionists that individuals, particularly children, might be exposed to excessive, potentially harmful levels of Vitamin D. Following extensive consultation with health professionals, the food industry and other interested parties, regulations were promulgated in 1964, extending control over the addition of vitamins, mineral nutrients and amino acids to all foods. Details are outlined in Table 7.

History of Canada's Enrichment Policy

Much of the early history of nutrient addition to foods concerned itself with flour. In the 1930s and early '40s, there was growing concern that the efforts by flour millers to produce "whiter" flours, with better baking characteristics, and higher consumer appeal was at the same time resulting in products from which significant quantities of the B

vitamins and mineral nutrients were being removed. Throughout the 1940s a debate ensued as to whether the addition of vitamins should be permitted to compensate for this loss or whether the more appropriate policy was to encourage the production of higher extraction flours. In the early stages, the latter position prevailed, but by the beginning of the 1950s, a number of factors influenced a change in thinking, including the entry of Newfoundland into Confederation in 1949, and the resultant disparities in requirements between that province and all others.

Situation in Newfoundland

A nutrition survey conducted in Newfoundland in 1944 revealed widespread malnutrition on the island. The government quickly enacted laws making mandatory the enrichment of white flour with certain B vitamins, iron and bonemeal (source of calcium). A second survey taken in 1948 revealed a general improvement in nutritional well-being of Newfoundlanders. How much of this can be attributed to enriched flour is difficult to ascertain, but it is generally believed that enrichment of flour played an important role in reducing this malnutrition.

When Newfoundland joined Canada, one of the conditions of confederation was that compulsory enrichment of white flour be continued.

The situation existed, therefore, that enrichment of white flour was compulsory in one Canadian province (Newfoundland) but was not allowed in the nine others. Millers and bakers were strongly in favour of the enrichment of white flour, and finally, as a result of widespread support, amendments to the *Food and Drug Regulations* were promulgated in 1952.

Current Policy on the Addition of Nutrients to Food

Today the *Food and Drug Regulations* permit or make mandatory the addition of a nutrient to a food when there is a need:

- to correct a demonstrated nutrient deficiency in some segment of the population, providing the addition of the nutrient is the most effective means to alleviate this problem and providing the food is a suitable vehicle for the nutrient and reaches the population that needs it. For example, the *Regulations* require mandatory addition of iodine to table salt (B.17.003) and vitamin D to milk (B.08.003–023). The amount that may be added is only sufficient to correct the deficiency.
- to replace those nutrients lost from food during processing in the course of good manufacturing practice, e.g. white flour.
- to ensure the nutritional quality of those products sold as sole sources of nourishment or as substitutes for traditional foods. Foods which may be sole sources of nourishment must contain essential nutrients, including energy in amounts related to the

purpose of the food, e.g. meal replacements, infant formulas (human milk substitute) and formulated liquid diets. Substitutes for a traditional food should be nutritionally comparable to the products they replace (e.g. meat substitutes – see Chapter 3, Table 4).

This policy is aimed at preventing nutrient deficiencies and maintaining or improving the nutritional quality in the food supply. The enrichment of foods is a preventative health measure; an understanding of the nutritional status and eating patterns of Canadians is necessary for it to be effective.

The foods to which vitamins and minerals may be added are listed in Table 7, with an asterisk indicating mandatory enrichment. The second column in Table 7 lists the vitamin, mineral nutrient or amino acid which may be added to specific foods. The third column presents the levels of these added nutrients which must be present in the food or indicates where this information may be found in the *Regulations*.

Table 7: Foods to Which a Vitamin, Mineral Nutrient or Amino Acid May Be Added

Food	*Vitamin, mineral nutrient or amino acid*	*Limits*	
*Table salt, table salt substitutes	Iodine	0.01% Potassium iodide	
Vegetable drinks, bases and mixes for vegetable drinks, and a mixture of vegetable juices	Vitamin C	As stated in Table 8	
Fruit nectars, apple juice, reconstituted apple juice, grape juice, reconstituted grape juice, pineapple juice, reconstituted pineapple juice, concentrated fruit juice, apple and any juice described in section B.11.132	Vitamin C	As stated in Table 8	
*Fruit-flavoured drinks and bases, concentrates and mixes that are used for making fruit-flavoured drinks and that are sold as a substitute for fruit juice or as a breakfast drink	Vitamin C, folic acid, thiamine, iron, potassium	100 mL of the ready-to-serve drink must contain:	
		Vitamin C	24–48 mg
		and may contain:	
		folic acid	40–80 mg
		thiamine	0.08–0.11 mg
		iron	0.56–0.80 mg
		potassium	100–200 mg

* Mandatory enrichment
** Addition of vitamin D is optional.
*** Addition of vitamin E is optional.

Food	*Vitamin, mineral nutrient or amino acid*	*Limits*
Dehydrated potatoes	Vitamin C	As stated in Table 8
Simulated meat or poultry products and meat or poultry product extenders	Thiamine, riboflavin, niacin, pyridoxine, pantothenic acid, folic acid, vitamin B_{12}, iron, magnesium, potassium, zinc, copper, histidine, isoleucine, leucine, lysine, phenylalanine, threonine, valine, methionine, tryptophan	See Table 5
Simulated whole egg	Vitamin A, thiamine, riboflavin, niacin, pantothenic acid, vitamin B_6, vitamin B_{12}, folic acid, alpha-tocopherol, calcium, iron, zinc, potassium	See page 28
Ready breakfast, instant breakfast and other similar breakfast replacement foods	Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin C, iron	As stated in Table 8
*Margarine and other similar ***substitutes for butter	Vitamin A, vitamin D, alpha-tocopherol (vitamin E)	100 g of margarine must contain not less than: Vitamin A 3300 I.U. Vitamin D 530 I.U. and may contain: alpha-tocopherol 0.6 I.U per g linoleic acid
*Milk, **condensed milk, milk powder, flavoured milk, sterilized milk	Vitamin D	852 mL (R.D.I.) of the ready-to-serve product must contain:
*Skim milk, partly-skimmed milk, skim milk powder: flavoured or not or with added milk solids	Vitamin A, vitamin D	Vitamin D 300–400 I.U. Vitamin A where required 1200–2500 I.U.
*Evaporated milk	Vitamin C, vitamin D	Vitamin C (where required) 60–75 mg
*Evaporated or concentrated skim milk or partly-skimmed milk	Vitamin A, vitamin C, vitamin D	

* Mandatory enrichment
** Addition of vitamin D is optional.
*** Addition of vitamin E is optional.

Food	*Vitamin, mineral nutrient or amino acid*	*Limits*
Flavoured beverage mixes and bases recommended for addition to milk	Vitamin A, thiamine, niacin or niacinamide, vitamin C, iron	Aa stated in Table 8
*Prepared infant formulas and simulated liquid diets	Biotin, folic acid, d-pantothenic acid, riboflavin, thiamine, alpha-tocopherol, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin K, calcium, chloride, copper, iodine, iron, manganese, phosphorus, potassium, sodium, zinc, amino acids, magnesium	As described in section B.24.102 and B.25.054 (see Table 6, page 29)
Infant cereal products	Thiamine, niacin or niacinamide, riboflavin iron, calcium, phosphorus, iodine	As stated in Table 8
Breakfast cereals	Thiamine, niacin or niacinamide, vitamin B_6, folic acid, pantothenic acid, magnesium, iron	100 g breakfast cereal *may* contain: thiamine 2.0 mg niacin 4.8 mg vitamin B_6 0.6 mg folic acid 0.06 mg pantothenic acid 1.6 mg magnesium 160 mg iron 13.3 mg
Alimentary pastes (pasta)	Thiamine, niacin or niacinamide, riboflavin, iron	As stated in Table 8

* Mandatory enrichment
** Addition of vitamin D is optional.
*** Addition of vitamin E is optional.

Food	*Vitamin, mineral nutrient or amino acid*	*Limits*
*Flour or white flour	Thiamine, niacin or niacinamide, riboflavin, iron, vitamin B_6, folic acid, magnesium, calcium	100 g of flour must contain: thiamine 0.44–60.77 mg riboflavin 0.27–0.48 mg niacin 3.5–6.4 mg iron 2.9–4.3 mg and may contain vitamin B_6 0.25–0.31 mg folic acid 0.04–0.05 mg pantothenic acid 1–1.3 mg magnesium 150–190 mg calcium 110–140 mg
*Enriched vitamin B white flour	Thiamine, niacin or niacinamide, riboflavin, iron	Same as for flour
*Enriched bread	Nutrients come from the enriched flour that must be used in the making of enriched bread	100 g of enriched bread must contain not less than: thiamine 0.24 mg riboflavin 0.18 mg niacin 2.20 mg iron 1.76 mg and may contain not less than: vitamin B_6 0.14 mg folic acid 0.024 mg pantothenic acid 0.60 mg magnesium 90 mg calcium 66 mg
*Meal replacements whether or not they are sold or represented for use in a weight reduction diet	Calcium, chloride, copper, iodine, iron, magnesium, manganese, phosphorus, potassium, sodium, zinc, alpha-tocopherol, biotin, pantothenic acid, folic acid, niacin or niacinamide, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, riboflavin	As described in section B.24.200
*Food for fat-modified diets meeting the requirements of sections B.24.015 (d) i and ii	alpha-tocopherol (vitamin E)	Not less than 0.6 I.U. per g linoleic acid

* Mandatory enrichment
** Addition of vitamin D is optional.
*** Addition of vitamin E is optional.

The Amount of Nutrient Added

In order to ensure that the enrichment of a food will be effective, and at the same time to prevent an excess intake of an added nutrient, the *Regulations* state the amount of nutrient that must be present in the food at the time of purchase.

There are two types of *Regulations*:

- specific regulations for certain foods, e.g. substitutes for traditional foods and processed products where the objective is to restore or increase the nutritional value of the food, e.g. flour, partly skimmed milk, etc.;
- general regulations stating the minimum and/or maximum amounts of certain nutrients that must be present in certain foods if that nutrient is added. Quantities are based on the Reasonable Daily Intake of that food. These quantitative limits are set out in Table 8.

Form of Added Nutrients

The physical and chemical characteristics of an added nutrient may affect its bioavailability. One example is the mineral nutrient, iron. Research has shown that the bioavailability of elemental iron powders is influenced by the particle size, and that the bioavailability of poorly-absorbed iron salts, such as sodium iron pyrophosphate, can be markedly improved by certain types of processing.

The *Food and Drug Regulations* have recently been amended to require that:

Table 8: Quantitative Limits for the Addition of Certain Nutrients to Foods

Nutrient	*Minimum in a R.D.I.*	*Maximum in a R.D.I.*	*Minimum in a R.D.I. if food is intended for children under 2*
Vitamin A	1600 I.U.	2500 I.U.	1000 I.U.
Vitamin D	300 I.U.	400 I.U.	300 I.U.
Vitamin E	–	15 I.U.	5 I.U.
Vitamin C	20 mg	60 mg	20 mg
Thiamine	0.6 mg	2 mg	0.4 mg
Riboflavin	1 mg	3 mg	0.6 mg
Niacin	6 mg	20 mg	4 mg
Pyridoxine	–	1.5 mg	0.6 mg
Calcium	300 mg	–	
Phosphorus	300 mg	–	
Iron	4 mg	–	
Iodine	0.10 mg	–	

- elemental iron powders, i.e., carbonyl iron, electrolytic iron and reduced iron, added to foods as a source of iron, meet certain particle size and purity specifications.
- when sodium iron pyrophosphate is added as a source of iron, the resultant bioavailability of the iron in the food be not less than 50 per cent that of ferrous sulphate, a well-absorbed form of iron.

Enrichment Practices in the U.S.A.

The American practices pertaining to vitamin and mineral enrichment of certain foods differ from those in Canada and adjustment should be made when using American food tables to calculate the nutritive value of a product.

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Material available from the Food Directorate, HPB:
Addition of Nutrients to Foods – Dispatch No. 49.
Recommended Nutrient Intakes for Canadians – Dispatch No. 54.

Chapter 5

Foods for Special Dietary Use

Division 24 of the *Food and Drug Regulations* deals with foods for special dietary use. Compositional requirements have been established to ensure that, when used properly, these foods should benefit consumers on special diets by increasing the quantity or the variety of foods permitted in their diets. Comprehensive labelling requirements provide the consumer, the dietitian, the physician and the nurse with information to make decisions on the appropriate use of these products.

Definition

According to B.24.001, "food for special dietary use" means a food that has been specially processed or formulated to meet the particular requirements of a person (a) in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or (b) for whom a particular effect, including, but not limited to weight loss, is to be obtained by a controlled intake of foods.

Classes of Foods for Special Dietary Use

There are a limited number of conditions for which the use of special foods may be necessary or advantageous. Accordingly, to avoid the proliferation of products recommended for all sorts of fad diets, the *Regulation* (B.24.003) specifies clearly what types of foods may be represented for special dietary use as follows.

(a) Foods represented for:
    Gluten-free diets
    Protein-restricted diets
    Low-(naming the amino acid) diet

There are no specific regulatory requirements for composition or labelling of these products.

(b) Foods for which the compositional and labelling requirements are set out in the *Regulations*:
Carbohydrate-reduced foods
Fat-modified foods
Sugar-free foods
Low-fat foods
Calorie-reduced foods
Formulated liquid diet foods
Low-calorie foods
Low-sodium foods
Meal replacements for use in weight reduction diets
Prepackaged meals for use in weight reduction diets

Compositional requirements for these special dietary foods are as follows:

Carbohydrate-reduced food: (B.24.004)
- may be made providing the original product derives at least 25 per cent of its energy value from carbohydrates;
- may not contain more than 50 per cent of the available carbohydrate present in the food for which it is a substitute;
- may not contain more calories than the food it replaces.

Sugar-free or Sugarless food: (B.24.005)
- is a carbohydrate-reduced food;
- may not contain more than 0.25 per cent of available carbohydrate;
- may not provide more than one calorie per 100 g or 100 mL except for chewing gum.

Calorie-reduced food: (B.24.006)
- may not contain more than 50 per cent of the calories provided by the original food.

Low-calorie food: (B.24.007)
- is a calorie-reduced food;
- may not provide more than 15 calories per average serving and 30 calories in a Reasonable Daily Intake (R.D.I.).

Low-sodium food: (B.24.008)
- may not contain more than 50 per cent of the sodium present in the food for which it is a substitute;
- may not contain more than 40 mg sodium/100 grams except for meat, fish, and poultry which shall contain not more than 80 mg sodium/100 grams, and cheddar cheese which shall contain not more than 50 mg sodium/100 grams;

- may not contain added salts of sodium except in the case of salt substitutes.

Food for fat-modified diet: (B.24.015)
- must be simulated meat products, simulated poultry products or yolk-replaced eggs meeting the requirements set out in the *Regulations;*
- may not contain more than 3 mg cholesterol per 100 grams of food;
- if labelled "low fat" may not contain more than 15 calories from fat in a serving or 30 calories from fat in a R.D.I.;
- if labelled "fat-modified" may not contain less than 40 per cent of total fat as linoleic acid (essential fatty acid) and not less than 0.6 I.U. of alpha-tocopherol (Vitamin E) per gram of linoleic acid; the total saturated and trans fatty acid content shall not exceed the linoleic acid content.

Formulated liquid diets (B.24.100)
- are nutritionally complete foods for oral or tube feeding of individuals in whom a physical or physiological condition exists as a result of disease, disorder or injury;
- may not be advertised to the general public;
- must meet the nutritional requirements set out in section B.24.100 of the *Regulations*.

Meal replacements for weight reduction (B.24.200)
- are single foods sold or advertised as a replacement for one or more daily meals;
- are represented for use in a weight reduction diet;
- must provide at least 225 calories per serving and be accompanied by directions for use which will result in the daily intake of at least 900 calories from the meal replacement alone or in combination with other foods (sample menu plan);
- must contain a calcium to phosphorus ratio of at least one;
- must contain, per serving, the vitamin and mineral nutrients listed in Table 9 on page 44;
- must contain between 20 and 40 per cent of energy as protein of an acceptable quality;
- may not contain more than 35 per cent of energy as fat and not less than three per cent as linoleic acid, an essential fatty acid;
- may not contain more than 30 per cent of available carbohydrate in the form of sucrose or fructose, except when the meal replacement is a cookie or biscuit.

Table 9: Vitamin and Mineral Requirements for Meal Replacements

	Minimum per serving	*Maximum per serving*
Vitamins		
Vitamin A	1,250 I.U.	2,500 I.U.
Vitamin D	25 I.U.	50 I.U.
Vitamin E	3.5 I.U.	7 I.U.
Vitamin C	7.5 mg	15 mg
Thiamine	375 mcg	750 mcg
Riboflavin	425 mcg	850 mcg
Niacin	5 mg	10 mg
Vitamin B_6	0.5 mg	1 mg
Vitamin B_{12}	0.75 mcg	1.5 mcg
Folic acid	50 mcg	100 mcg
Biotin	10 mcg	20 mcg
D-pantothenic acid	1.25 mg	2.5 mg
Minerals		
Calcium	200 mg	400 mg
Phosphorus	200 mg	400 mg
Iron	3.5 mg	7 mg
Iodine	35 mcg	70 mg
Magnesium	75 mg	150 mcg
Copper	0.5 mg	1 mg
Zinc	2.5 mg	–
Potassium	375 mg	–
Manganese	0.65 mg	1.3 mg
Sodium	250 mg	–

Prepackaged meals for use in weight reduction (B.24.201)

- are prepackaged selections of foods for one individual that require no preparation other than heating;
- are represented for use in a weight reduction diet;
- must contain at least two average-sized servings from two different food groups;
- must be accompanied by directions for use which would result in the intake of at least 900 calories per day (sample menu plan).

Labelling

Besides general labelling requirements outlined in Chapter 2, the label of special dietary foods shall include additional information as outlined in Table 10.

Table 10: Class of Food for Special Dietary Use

Label Information	*Carbohydrate-reduced*	*Sugar-free*	*Calorie-reduced*	*Low-calorie*	*Low-sodium*	*Low-fat*
Energy	+	+	+	+	+	+
Protein	+	+	+	+	+	+
Fat	+	+	+	+	+	+
Carbohydrate	+	+	+	+	+	+
Sorbitol	+	+	+	+		
Mannitol	+	+	+	+		
Polydextrose	+	+	+	+		
Sodium					+	+
Potassium					+	+
Cholesterol						+
Linoleic acid						
Saturated fatty acids						
Saturated and trans fatty acids						
Crude fibre						
Vitamins						
Minerals						

Table 10 (Cont'd): Class of Food for Special Dietary Use

Label information	*Fat-modified*	*Formulated liquid diet*	*Meal replacement*	*Prepackaged meal for weight reduction*
Energy	+	+	+	+
Protein	+	+	+	+
Fat	+	+	+	+
Carbohydrate	+	+	+	+
Sorbitol				
Mannitol				
Polydextrose				
Sodium	+	+	+	
Potassium	+	+	+	
Cholesterol	+			
Linoleic acid	+	+	+	
Saturated fatty acids	+			
Saturated and trans fatty acids	+			
Crude fibre		+		
Vitamins		+	+	
Minerals		+	+	

Mannitol, Sorbitol and Xylitol

Because of their slow absorption rate, mannitol, sorbitol and xylitol are not considered available carbohydrates, and although their presence is indicated on the label, they are not accounted for in the quantitative carbohydrate declaration. However, their energy value is included in the total energy value of the product and is calculated as two calories per gram of mannitol and four calories per gram of sorbitol or of xylitol.

Other Mandatory Information

- Meal replacements and prepackaged meals recommended for use in a weight reduction diet must carry the statement that adherence to the directions for use may reduce energy intake that could result in weight loss. This is to avoid the impression that a specific ingredient in the food may be responsible for the weight loss.
- Meal replacements and prepackaged meals recommended for use in weight reduction, except those meal replacements recommended as replacements for all meals in the diet, must include as part of the directions for use a sample seven-day menu, which meets the nutrient requirements set out in the *Regulations*. All four food groups must be represented each day.
- The menu or label shall not include any reference to vitamin and/or mineral supplements.

Other Claims

Non-cariogenic: Foods which meet the criteria for "sugar free" may be described as "non-cariogenic" or by a synonymous term.

"Made without salt" or "No salt added" label statement : These are acceptable claims if true and if the product normally contains salt. These are considered claims for sodium content and require a declaration of the sodium and potassium content (expressed in mg per 100 g or per 100 mL).

"No sugar added" label statements: Such statements as "unsweetened", "sweetened", "sweetened without sugar", "sugar added", "sugarless" and "no sugar added" are considered claims for carbohydrate or sugar content. The label of the food requires a statement of the carbohydrate content in grams per 100 g, per 100 mL or on a percentage basis (B.01.034).

Liquid protein preparations: Foods represented as containing hydrolyzed or partially hydrolyzed collagen, gelatin or casein must carry the statement "Caution do not use as the sole source of nutrition." This *Regulation* does not apply to formulated liquid diets or infant formulas.

Regulations Pertaining to the Use of Synthetic Sweeteners

Sugar substitutes containing cyclamates or saccharin are sold as table-top sweeteners, but these two artificial sweeteners are not permitted in processed foods in Canada. Saccharin may only be sold to the general public on the premises of a pharmacy.

Aspartame, a non-carbohydrate nutritive sweetening substance, is 180-200 times sweeter than sugar. Since 1981 it has been permitted in table-top sweeteners and in a number of processed foods, such as breakfast cereals, beverages including soft drinks, beverage concentrates and mixes, desserts, dessert mixes, toppings and fillings, and chewing gum.

The label of food that contains aspartame shall carry a statement on the principal display panel that the food contains aspartame, and elsewhere on the label, a statement that aspartame contains phenylalanine, as well as the energy value in calories and the content of protein, fat, carbohydrate and aspartame per 100 g or per 100 mL of the food as sold or per unit of ready-to-serve food.

The label of any sweetener that contains aspartame shall carry, in addition to the above information, a statement of the sweetness per serving expressed in terms of amount of sugar required to produce an equivalent degree of sweetness.

Bibliography

The Food and Drugs Act and Regulations may be purchased from:
Canadian Government Publishing Centre
Supply and Services Canada
Ottawa, Canada
K1A 0S9

Material available from the Food Directorate, Health Protection Branch:
Sweeteners from A to X – Dispatch No. 53.
Meal Replacements for Weight Loss Programs – Dispatch No. 57.

Chapter 6

Recommended Nutrient Intakes (RNI) for Canadians

In 1983, the publication *Recommended Nutrient Intakes for Canadians* was issued replacing the 1975 *Dietary Standard for Canada*. The new document was prepared by an *ad hoc* Advisory Committee and represents the efforts of more than 40 Canadian nutritionists who reviewed the scientific literature on human requirements for energy and nutrients.

To set a recommended nutrient intake, the committee considered the requirement of a nutrient to be the level of dietary intake that permits the establishment and maintenance of a reasonable level of body stores. The recommended intake is an estimate of the level of dietary intake of a nutrient that meets the requirements of almost all individuals within a specific physiological group (age, sex, body size, physical activity, type of diet). It is assumed that the requirements of the group are normally distributed and that the average value plus two standard deviations (30%) is an appropriate recommended intake for a nutrient. The RNI, therefore, exceeds the requirement for most people.

The rate of intake is expressed on an average daily basis, but the recommended amount per day need not be ingested each day so long as the average intake is at the appropriate level. In practical situations, intakes vary from day to day.

Requirements for thiamine, riboflavin, niacin and essential fatty acids are related to energy, and vitamin B_6 is proportional to protein intake. The RNI for ascorbic acid is raised from 30 mg per day to 60 mg for adult males and 45 mg for adult females. Thiamine has been lowered by 20 per cent to 0.1 mg per 1000 kJ of energy. Iron for the pregnant woman, who is likely to have low iron stores, is recommended at the level of 20 mg per day. In addition, new data on infants led to revised estimates of requirements that more closely approximate the nutrient and energy intake of breastfed babies.

It is expected that the document will be useful for those planning diets for different groups and situations and to guide the development of various food and nutrition policies.

The Canadian Nutrient File

Tables of nutrient composition of foods are basic to all food composition and dietary intake studies. The Canadian Nutrient File is a compilation of all the best available data on the nutrient composition of foods consumed in Canada. Much of the information has been derived from *Handbook No. 8* of the United States Department of Agriculture (USDA), which has now become an international resource; some of the USDA material is Canadian in origin, while other data, although from the U.S., are considered to be applicable to Canadian foods, or can be adapted and extended.

As new nutrient values become available for Canadian foods, they are added to the file which is stored on computer tape and is accessible in any computer language. The file is updated annually.

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Canadian Nutrient File (1600 BPI, 9-track computer tape, $105.). Available from:
P. Verdier, Bureau of Nutritional Sciences
Sir Frederick Banting Building
Tunney's Pasture
Ottawa
K1A 0L2

Material available from the Food Directorate, Health Protection Branch:
Recommended Nutrient Intakes for Canadians – Dispatch No. 54.

Chapter 7

Microbial and Extraneous Material Contamination of Food

Microbial and extraneous matter contamination of foods is a very important public health concern. A variety of microorganisms are capable of causing infections and intoxications that may be mild in nature or be serious enough to cause death. Other microorganisms may themselves not be harmful, but may indicate the possible presence of pathogenic organisms or be an indication of unsanitary processing and handling conditions. Still others cause spoilage of food, and unnecessary wastage.

Extraneous matter in food may merely indicate unsanitary practices or conditions, or, as for example in the case of metal or glass fragments, represent a health concern in their own right.

Aside from the injury and illness that may arise from microbial and extraneous matter contamination of food, there is the attendant economic cost resulting from medical treatment and hospitalization, loss of work time and productivity, and wastage of food.

The Health Protection Branch has an active program of research, evaluation, surveillance and compliance to combat the problems associated with this type of contamination.

Pathogens

Pathogenic microorganisms are those capable of producing illness. Food-borne illness occurs frequently in Canada – some estimate that there are more than 500 000 cases of food poisoning each year – and is due mainly to poor food handling practices in food service establishments and in the home.

Current problems with food-borne disease are closely associated with a number of features of modern day food processing, handling and

distribution. The food industry has become more and more concentrated, with foods from one source now reaching a much wider area.

Any breakdown in the food handling system, from the producer to the consumer, can put thousands of people at risk. In a recent example, when an improper pasteurization procedure was used in a Canadian dairy, *Salmonella*-contaminated milk was used for cheese production; the contaminated cheese was shipped throughout Canada and hundreds of people became ill.

The pathogens most commonly involved in food-borne illness are *Salmonella*, *Staphylococcus aureus*, *Clostridium perfringens*, *Bacillus cereus*, and *Campylobacter*, all of which cause gastroenteritis among other symptoms (see Table 11).

Although, in general, most episodes of food poisoning last only a few days, patients with salmonellosis can be ill for many weeks, and for some, such as the debilitated, aged or infants, the illness may be fatal. It is estimated that salmonellosis costs Canadians about $150 million a year in hospitalization costs and lost income.

Two recently recognized pathogens are *Campylobacter* and *Yersinia enterocolitica*. Water and raw (unpasteurized) milk are the main sources of *Campylobacter*, but it may also be found in some foods. Victims of campylobacteriosis may be ill for many weeks. *Yersinia* has been associated with a variety of human illnesses. The organism is found in the intestines of animals, including pets and farm animals and also lives freely in spring water. *Yersinia* has been identified in chocolate, powdered and pasteurized milk, and in tofu and bean sprouts prepared with contaminated spring water.

The toxin produced by *Clostridium botulinum* can cause serious illness or death when the organism grows in improperly-processed low-acid foods such as canned meat and vegetables and when these foods are subsequently consumed without further cooking. Cooking to 100°C for 10 minutes will destroy the toxin. In the case of infant botulism, the organism produces toxin directly in the gut of the child. Fortunately, botulism is rare in commercially-processed food products.

As a precautionary measure, the mushroom industry has recently been advised to perforate plastic film used to wrap fresh mushrooms, in order to avoid the possible formation of botulinal toxin. Although the chances of botulism poisoning from this source are remote, it was determined that if these packages, which quickly become anerobic, are temperature-abused when stored at room temperature for several days, any *C. botulinum* spores present could multiply and produce botulinal toxin.

Some viral diseases are also food borne. Current methodology is largely inadequate in its ability to detect viruses in food. Hepatitis A, though, has been implicated in illness resulting from consumption of polluted water, raw milk and raw shellfish harvested from water contaminated by sewage. Transmission to other food is often via infected food handlers.

Trichinosis is a food-borne infection cause by the parasitic worm *Trichinella spiralis* which is occasionally found in raw pork and bear meat. Thorough cooking will destroy the organism.

Table 11: Selected Pathogens Causing Food-borne Illnesses

Disease & food-poisoning agent	*Frequency of symptoms*	*Habitat & foods commonly involved*
Staphylococcal food poisoning caused by toxins produced by *Staphylococcus aureus*; toxins resistant to boiling	Frequent; death is rare. Cramps, nausea, diarrhea, vomiting. Onset 1–6 hrs. after eating; duration one day	Found in nose and throat of most people; foods (ham, cooked poultry, meat or potato salads, fish, cream desserts)
Botulism caused by toxins of *Clostridium botulinum*; grows in absence of air; toxin destroyed by boiling; produces heat-resistant spores that survive boiling	Rare; death may occur. Double vision, dry mouth, nervous system affected, paralysis. Onset 1 day to 1 week after eating; recovery slow	Found in most soils; foods (underprocessed home-canned or commercial vegetables, fish & meats; aged meat or fish eaten by native people)
Perfringens food poisoning caused by *Clostridium perfringens*; grows in absence of air; produces heat-resistant spores	Frequent; death is rare. Diarrhea, cramps Onset 8–24 hrs. after eating; duration one day	Found everywhere, especially in gut of animals; foods (meats, stews, gravies, especially in bulk quantities)
Salmonellosis caused by many different types of *Salmonella*; can also be spread by person-to-person transmission	Frequent; occasional death for infants, aged and infirm persons. Cramps, vomiting, chills, diarrhea, fever. Onset 8–24 hrs. after eating; duration usually 2–3 days, but illness may last for weeks	Found in gut of domestic animals, e.g., chicken and pigs; foods (poultry, meat and egg products, raw milk)

Disease & food-poisoning agent	*Frequency of symptoms*	*Habitat & foods commonly involved*
Bacillus cereus poisoning caused by *Bacillus cereus*; produces heat-resistant spores that survive in dust and soil	Fairly frequent; death unknown; two types. *Type 1* Nausea, diarrhea, cramps. Onset 8–16 hrs. after eating; duration one day	Found everywhere, e.g. dust, soil; foods (cereal products, custards, meat loaf, chicken à la king)
	Type 2 Nausea, vomiting. Onset 1–6 hrs, after eating; duration one day	Found everywhere, e.g. dust, soil, foods (rice, particularly Chinese-type food)
Hemorrhagic colitis caused by certain strains of *Escherichia coli*; this disease has only recently been recognized	Infrequent. Abdominal cramps, bloody diarrhea, edema of cecum and colon Onset 12–36 hrs. after eating; duration several days	Probably intestinal tract of animals, food (contaminated ground meat)
Infectious hepatitis (jaundice) caused by Hepatitis A virus	Frequent. Fever, headache, lassitude, malaise, lack of appetite, nausea, vomiting, jaundice Onset 25–30 days after eating; duration several weeks	Sewage-polluted water, milk, raw shellfish
Trichinosis caused by *Trichinella spiralis*; the parasite multiplies in the intestine, then migrates to muscle tissue to form relatively heat-resistant cysts	Relatively infrequent; death may occur; severity depends on quantity of cysts ingested Gastroenteritis, muscle pain, fever, swelling around the eyes, weakness Onset 4–28 days; duration several weeks	Found in muscles of carnivorous or omnivorous animals; foods (improperly cooked, frozen or fermented meat of the above, particularly pork and bear meat)
Mushroom poisoning caused by a variety of mushrooms, e.g. *Amanita* spp. (fly agaric, destroying angel); only some toxins destroyed by cooking	Infrequent; may be fatal Abdominal pain, bloody vomitus, diarrhea, convulsions Onset a few minutes to several hours after eating; duration 1–2 days	Growing wild

Disease & food-poisoning agent	*Frequency of symptoms*	*Habitat & foods commonly involved*
Paralytic shellfish poisoning caused by ingestion of toxic dinoflagellates by shellfish	Sporadic from shellfish gathered on east and west coasts of Canada; death may occur Tingling of lips, face, arms and legs, inability to stand, paralysis of respiratory muscles. Onset 30 min. to 3 hrs after eating; duration 1–2 days	Coastal waters during summer and fall. Levels of toxin in shellfish are continually monitored and harvesting banned if levels are too high
Scombroid poisoning caused by bacteria in fish gut, producing histamine; poison heat resistant	Infrequent; death unknown. Headache, nausea, dizziness, rapid pulse, flushing of face Onset a few minutes to several hours after eating; duration 1 day	Scombroid fish such as tuna, mackerel; also mahi-mahi (Pacific dolphin); food (frozen, smoked or canned fish of above species)
Yersiniosis caused by *Yersinia enterocolitica*; large number in raw milk may allow survival in pasteurized product; growth occurs at refrigeration temperatures	Rare. Abdominal pain as if caused by acute appendicitis, fever, headache, vomiting, diarrhea Onset 24–36 hrs. after eating; duration usually 2–3 days, but may last for 1–4 weeks	Found in pigs, chickens, dogs, rodents, soil and water. Water, raw milk and pasteurized milk contaminated from dirty crates have caused illness
Campylobacteriosis caused by *Campylobacter jejuni* and *C. coli*; can also be spread by person-to-person transmission, particularly in day-care nurseries	Infrequent. Cramps, diarrhea, fever, nausea, vomiting, headache, weakness Onset usually 3–5 days after eating; duration 1–5 days but may last for 2 weeks	Found in infected domestic animals and water. Raw milk and water are the main sources of food-borne campylobacteriosis

All microbiological illnesses can be prevented by (a) reducing the contamination of food as much as possible, using good quality ingredients and sanitized equipment, (b) by not allowing the organisms to grow (keeping food hot or cold with as little preparation at room temperature as possible), and (c) by not consuming food that is obviously spoiled or in swollen containers.

Illnesses caused by parasites can be prevented by using approved sources of meat and cooking thoroughly.

Food poisoning caused by poisonous plants or animals can be avoided by knowing toxic species (plants), keeping seeds of these plants well away from food preparation areas, and observing notices banning collecting of shellfish (paralytical shellfish poison); unfortunately scombroid poison is not easily recognized by smell or taste but the occurrence is rare in fish sold in Canada.

Some chemical poisonings can be prevented by keeping pesticides and other chemicals out of the kitchen, and by rejecting any food that smells, tastes or appears abnormal.

Fungal Toxins

Mycotoxins are toxic substances produced by moulds growing on foods such as field crops and fruit at the time of harvest or on these and other foods, such as cheese, during storage. Poisoning by these substances is called mycotoxicosis. This subject is dealt with more fully in Chapter 8.

Indicator Organisms

Escherichia Coli is a common organism of the human and animal intestinal tract, and its presence in food is an indication of fecal contamination, and, therefore, of the potential presence of such pathogens as Salmonella. Some strains, however, are capable of causing illness such as hemorrhagic colitis and infantile diarrhea.

In other cases, an indication of improper processing or handling may be given by the presence of excessively high total counts of bacteria even though the types of bacteria involved are merely spoilage organisms.

Spoilage Organisms

The vast majority of bacteria, yeasts, and moulds are not pathogenic to humans. Nevertheless, excessive numbers of them can cause spoilage and render the food unfit for consumption. Often, this spoilage acts as a safeguard, in that it leads to rejection of food that may also be contaminated with pathogenic microorganisms or their toxins.

The reverse is not true, however. Foods may contain unsafe levels of bacteria or their toxins without any visible signs of deterioration. It is important, therefore, that perishable foods subject to contamination by pathogens not be abused at any stage leading up to consumption.

Extraneous Matter

Extraneous matter includes insects and insect fragments, rodent hair, feather barbules, animal droppings, filth of a variety of sorts, metal fragments and glass.

Although contamination of food with extraneous matter is generally not as serious a public health problem as is contamination with pathogenic or toxigenic bacteria and moulds, it nevertheless occupies an important place in food control.

Its presence in foods is an indication of poor manufacturing practice and lack of quality control. It is generally highly visible and esthetically unappealing to the consumer and is a source of many, if not the majority, of complaints received by the Health Protection Branch. The occurrence of extraneous matter may also be an indication of the presence of pathogens. Finally, metal fragments, wood splinters and glass particles may, in themselves, be hazardous.

Regulatory Control

For the most part, action against the presence of microbial and extraneous matter contamination is taken on the basis of the *Food and Drugs Act* itself (Section 4 as stated in Chapter 1).

To supplement this, it has been found necessary to write regulations, to deal with specific problems relating to both storage requirements and microbiological specifications. These are outlined in Tables 12 and 13. Additionally, the Health Protection Branch has recently developed a set of new *Regulations* giving greater control over commercially sterile low-acid foods in hermetically sealed containers (canned foods). This action was necessitated by the occurrence over the past few years of an increase in the number of unsatisfactory findings in the examination of these products. These *Regulations* will provide a firmer basis upon which to take action.

Table 12: Storage Requirements

Food	*Specifications*	*Reference*
Cheese from unpasteurized source	Stored 60 days at 2°C or above	B.08.030
Processed cheese products	Pasteurized at processing	B.08.030
Meat, meat products, in hermetically-sealed containers	Heat-processed to destroy toxin-producing microorganisms	B.14.013
Meat, meat products, in hermetically-sealed containers not heat processed to commercial sterility	Refrigerated, frozen, dehydrated, chemically preserved, or at a pH of 4.6 or less	B.14.014
Barbecued, broiled, roasted meat, poultry, etc.	Held at 4.4°C or 60°F prior to sale, and so labelled	B.14.072
Smoked fish and fish products, not cooked prior to eating, packaged in containers that have been sealed to exclude air	Heat-treated to destroy *Clostridium botulinum* spores, or must contain 9% salt, or remain frozen	B.21.025
Sterilized milk	Heat-treated to kill all viable microorganisms	B.08.007

Table 13: Microbiological Specifications

Food	*Specifications*	*Reference*
Cocoa and chocolate	Free from *Salmonella* as determined by official method MF0-11	B.04.010
Skim milk powder	Free from *Salmonella* as determined by official method MF0-12	B.08.014A
Flavoured milks	Not more than 50 000 bacteria per cc	B.08.016
Milk for manufacture	Not more than 2 000 000 bacteria per mL	B.08.025
Cheese made from a pasteurized source	Not more than 100 *Escherichia coli** or 100 coagulase positive *Staphylococcus aureus* per gram	B.08.048
Cheese made from an unpasteurized source	Not more than 500 *Escherichia coli** or 1000 coagulase positive *Staphylococcus aureus* per gram	
Cottage cheese	Not more than 10 coliform bacteria per gram	B.08.054
Ice cream and ice milk	Not more than 100 000 bacteria per gram or 10 coliforms per gram	B.08.062
Edible bone meal	Not more than 1000 bacteria per gram, no *Escherichia coli*	B.14.061
Gelatin	Free from *Salmonella*, not more than 5000 bacteria or 10 coliforms per gram	B.14.062
Fish protein	Not more than 10 000 bacteria per gram, no *Escherichia coli*	B.21.027
Frog legs	Free from *Salmonella* as determined by official method MFO-10	B.21.031
Egg product or liquid eggs	Free from *Salmonella* as determined by official method MFO-6	B.22.033
Water in sealed containers	Not more than 100 bacteria per mL, no coliforms	B.12.004
Prepackaged ice	No coliforms	B.12.005
Mineral water	No coliforms	B.12.001
Canned tomatoes, tomato juice and vegetable juice	Not more than 25% of microscopic fields containing mould filaments	B.11.016
Tomato purée, paste, pulp and catsup	Not more than 50% of microscopic fields containing mould filaments	B.11.017

**Escherichia coli* (a measure of human or animal fecal contamination) and coliforms(a measure of environmental contamination) are indicators of (1) the potential for pathogens to be present and (2) general sanitary quality.

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Material available from the Field Operations Directorate, Health Protection Branch:

Food Safety: It's all in your hands (booklet).

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Canned Foods: Keeping the lid on contamination (tearsheet).

Food Safety ... questions and answers on food safety (tearsheet).

Handling Poultry ... safely (tearsheet).

Cost of Food Poisoning (tearsheet).

Food Safety on the Run (tearsheet).

Microbial Food Poisoning – Dispatch No. 32.

Chapter 8

Food Chemical Contaminants

For the purposes of public safety, a food chemical contaminant is defined as any chemical substance present in a food, which was not intentionally added to the food, and which may pose a potential risk to public health. This definition encompasses substances that are naturally occurring (e.g. mycotoxins) as well as substances which may be inadvertently introduced or increased through human intervention (e.g. PCBs, lead, cadmium). It also includes substances which may be essential components of foods at certain levels but could pose a health hazard at increased levels (e.g. copper, iron).

Trace Elements

Trace elements are substances which are naturally present in the environment and may be classified as essential (e.g. copper, zinc, iron) or toxic (e.g. lead, cadmium, mercury). Low "background" levels of even the toxic trace elements may be found in most foods.

In addition, food may be contaminated with trace elements as a result of human activities such as industrial operations, automobile emissions and the application of urban waste as fertilizer.

The maximum tolerated levels for certain trace elements in foods offered to the Canadian consumer are listed in Table I, Division 15 (Table 14 on page 62).

One trace element of particular concern from a public health point of view is lead. Lead is a non-essential trace element that has no demonstrated beneficial action in animals or humans. At relatively low blood lead levels, alterations in blood biochemical parameters have been observed in both adults and children although the implications of these changes in terms of human health are unknown at this time. In

Table 14: Maximum Tolerance for Trace Elements

Substance	*Tolerance/ppm*	*Food*
Arsenic	0.2	Apple juice, cider, wine
	0.1	Beverages as consumed and water in sealed containers other than natural mineral water or mineral water
	1	Edible bone meal
	3.5	Fish protein
	0.1	Fruit juice except apple juice
Fluoride	650	Edible bone meal
	150	Fish protein
Lead	0.5	Apple juice, cider, wine
	0.2	Beverages as consumed and water in sealed containers other than natural mineral water or mineral water
	10	Edible bone meal
	0.15	Evaporated milk, condensed milk and concentrated infant formula
	0.5	Fish protein
	0.2	Fruit juice except apple juice
	0.08	Ready-to-serve infant formula
Tin	250	Canned foods

addition, relatively low level exposure has also been implicated in intellectual and behavioural deficits in children and considerable research is ongoing both in-house and internationally to resolve this issue. Because of the potential adverse effects of even low levels of lead on human health, a number of projects have been initiated by the Branch to determine the lead intake of various segments of the population and to assess the implication of these intakes and the need for regulatory controls. For example, since dietary lead is a major contributor to lead intake and one of the major sources of lead in the diet is the lead soldered can, the Branch has an active program to reduce lead levels in canned foods.

Mycotoxins

Mycotoxins (mycos in Greek for mould) are chemical compounds produced by some species of mould under certain temperature, moisture and storage conditions as was briefly mentioned in the previous chapter. Mycotoxins are persistent substances and may remain in a product even after the moulds which produced them are destroyed. The illness, disease or condition resulting from the intake of mycotoxin-contaminated food or feed is called *mycotoxicosis*.

Aflatoxins

Of all mycotoxins, aflatoxins are the most studied and regulated. Aflatoxins have been shown to cause an acute form of liver disease and liver cancer in experimental animals. Since aflatoxins are produced from naturally occurring moulds on crops and are not added to foods nor present because of human activities, it is impossible to eliminate all traces of these substances in foods without destroying the foods themselves. *Regulation* B.01.046(N) sets a limit of 15 parts per billion for aflatoxin in nuts and nut products. The Health Protection Branch has an active program aimed at minimizing aflatoxin levels in nuts and nut products since these commodities are susceptible to mould contamination and subsequent production of aflatoxin, and are the commodities of concern in the Canadian marketplace.

Vomitoxin

Another mycotoxin which has recently received some attention is deoxynivalenol or as it is more commonly called vomitoxin. This substance can be produced by a common mould which may affect cereal crops such as corn and wheat, and may have adverse health effects. In 1980, when this substance was discovered in grain crops grown in several parts of Eastern Canada, very little scientific information on vomitoxin was available. The Health Protection Branch, in cooperation with Agriculture Canada and the Canadian food industry, initiated a number of studies to determine levels occurring in crops and the stability of vomitoxin during food processing. In addition, toxicological studies in laboratory and farm animals were undertaken by the Branch and Agriculture Canada. At present, research continues in developing more sensitive analytical methods to detect vomitoxin (and other mycotoxins), in studying the long-term toxic effects of vomitoxin in mice, and in estimating the intake of vomitoxin in the human diet, so as to better assess the human health implications from this mycotoxin. Annual guidelines are set for maximum levels of vomitoxin in certain crops based on this research and on food processing studies.

Others

In addition to the compounds mentioned already, programs have been initiated to examine other mycotoxins (e.g. zearalenone, ochratoxin) which may also be of public health concern.

Chlorinated Hydrocarbons

There are two groups of the many chlorinated hydrocarbons which are of particular interest both at the international level and at the Health Protection Branch: polychlorinated dibenzoparadioxins (more commonly known as dioxins) and polychlorinated biphenyls, also known as PCBs.

Dioxins

Polychlorinated dibenzoparadioxins consist of a large number of related compounds differing only in the number and position of chlorine atoms in the molecule. The presence of dioxins in food results mainly from environmental contamination. Such contamination has been associated with the manufacture and subsequent application of certain agricultural chemicals. Another potential source of these compounds is the atmospheric deposition from industrial and municipal incineration of chlorinated substances. One particular member of this group is 2,3,7,8-tetrachlorodibenzoparadioxin or 2,3,7,8-TCDD. This compound is considered to be one of the most toxic substances known to man. For this reason, considerable research is being directed worldwide to determination of the presence of this toxic compound in food and assessment of its potential effects on human health. The Branch has developed analytical methodology sensitive to the parts per trillion range for dioxins in fish and has set a maximum limit for 2,3,7,8-TCDD of 20 ppt in fish. It has also coordinated an international study to compare the reliability of present analytical methods for this substance. In addition, scientists from the Branch have met with other federal, provincial and international agencies to share information regarding the toxicity of these chemicals and to discuss regulatory approaches for dealing with this problem.

PCBs

A number of polychlorinated biphenyls are also under investigation by Branch scientists.

PCBs are a family of industrial compounds which have been widely used in the past for many purposes such as paints, electrical transformers and capacitors. They were first identified as environmental contaminants around 1966 and subsequently it was discovered that with time the residues of these compounds could accumulate in components of the food chain, most notably fish. In addition, accidental leakage or spillage of PCBs from electrical equipment in food-processing establishments could cause contamination of food with these substances. Following these discoveries, a guideline level for PCBs in fish of 2 ppm was established and interdepartmental efforts, including an inspection program to advise food manufacturers of potential areas of PCB contamination, were initiated to reduce human exposure to these substances.

Since the consumption of PCB-contaminated fish by nursing mothers can result in the presence of PCBs in breast milk, a Committee of Canadian and American experts was established in 1978 to assess whether there are any problems related to the presence of PCBs in human milk. The committee concluded, based on toxicological data from animal studies that, in general, levels of PCBs in mothers' milk would not pose a hazard to suckling infants and in view of the benefits of breast-feeding recommended that this practice should be continued

and encouraged. In this regard, it should be noted that in a national survey conducted by the Health Protection Branch, PCB residues in mothers' milk in Canada were well below any level of concern in 98 per cent of the sample analysed. The committee did recognize, however, that certain women may have increased exposure to PCBs either industrially or as a result of the high consumption of fish and in these instances they recommended that the family physician should be consulted before initiating breast-feeding. At the present time there have been no reports of illness related to or attributed to PCBs in breast-fed infants.

Through the actions of the Health Protection Branch and other federal agencies, the use of these compounds has been restricted to closed electrical systems. Since these and other restrictive measures were taken, the level of PCBs present in the food chain has steadily declined. The Branch is continuing to conduct research programs to assess further the human health implications of these compounds to the Canadian consumer.

Others

The Branch also has programs to assess the health implications of other chemical substances which may be present in foods. These include asbestos, which occurs naturally in the environment and in the past was widely used as a filtering aid for beverages, and the family of polycyclic aromatic hydrocarbons, which occur primarily as products of the combustion of organic matter (e.g. coal burning, wood burning, smoking and broiling of meat).

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Chapter 9

Food Additives

Food additives serve a variety of functions depending on their nature and technical application. Many are used to enhance the keeping quality or stability of foods thereby resulting in reduced wastage and in the maintenance of nutritional quality. Others help make foods attractive to the consumer and provide essential aids in food processing. Without food additives many of the foods currently enjoyed would not be available.

The present regulations on food additives were established in 1964 when a "positive" list of additives (those which are permitted as opposed to those which are not) was first set out, following a review of all the information on the acceptability of such compounds. Provisions have always existed in the *Food and Drugs Act* for the prohibition of any substance which is considered to be unsuitable for use in foods; these provisions still exist and are described in Chapter 1.

According to the *Regulation* B.01.001 a food additive means "any substance, including any source of radiation, the use of which results, or may reasonably be expected to result in it or its by-products becoming a part of or affecting the characteristics of a food."

By this definition a food additive does not include:

- any nutritive material that is used, recognized or commonly sold as an article or ingredient of food;
- vitamins, mineral nutrients and amino acids;
- spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives;
- agricultural chemical residues;
- food packaging materials and components thereof;
- drugs recommended for administration to animals that may be consumed as food.

These substances are not included in the definition because *Regulations* in other Divisions govern their use.

Food Additive Regulations

The list of approximately 300 permitted food additives is set out in table form in Division 16. Each table lists the following:

- purpose;
- names of additives that can be used for that purpose;
- foods in which they are permitted;
- the amount permitted.

The following are examples of various food additives in each of the categories currently covered by the Tables in Division 16.

Anticaking Agents

Calcium silicate is permitted in salt up to a maximum level of 1.0%.

Magnesium stearate is permitted in unstandardized dry mixes in accordance with G.M.P. (Good Manufacturing Practice).

Bleaching, Maturing and Dough Conditioning Agents

Ammonium persulphate is permitted in unstandardized bakery foods in accordance with G.M.P.

Calcium peroxide is permitted in bread up to a maximum level of 100 parts per million (ppm) of flour.

Colouring Agents

b-apo-8′-carotenal is permitted in sherbet up to a maximum level of 35 ppm.

Tartrazine is permitted in unstandardized foods up to a maximum level of 300 ppm singly or in combination with Allura Red, Amaranth, Erythrosine, Indigotine or Sunset Yellow FCF.

Emulsifying, Gelling, Stabilizing and Thickening Agents

Agar is permitted in ice cream up to a maximum level of 0.5%.

Lecithin is permitted in sherbet up to a maximum level of 0.75%.

Disodium phosphate is permitted in cottage cheese up to a maximum level of 0.5%.

Food Enzymes

Invertase is permitted in confectionery in accordance with G.M.P.

Firming Agents

Potassium aluminum sulphate is permitted in pickles and relishes in accordance with G.M.P.

Glazing and Polishing Agents

Mineral oil and petrolatum are permitted in confectionery at a maximum level of 0.15%.

Miscellaneous

Aspartame as a sweetener and flavour enhancer is permitted in beverages up to a maximum level of 0.1%.

Magnesium silicate is permitted in chewing gum as a dusting agent in accordance with G.M.P.

pH Adjusting Agents, Acid-reacting Materials and Water-correcting Agents

Citric acid is permitted in unstandardized foods in accordance with G.M.P.

Lactic acid is permitted in cottage cheese in accordance with G.M.P.

Preservatives

Ascorbic acid (vitamin C) is permitted in preserved meat and poultry in accordance with G.M.P.

Benzoic acid is permitted in jam up to a maximum level of 1000 ppm.

Sequestering Agents

Disodium EDTA is permitted in dressing and sauces up to a maximum level of 70 ppm.

Starch-modifying Agents

Sodium hydroxide is permitted in starch in accordance with G.M.P.

Food Additives Used as Yeast Foods

Ammonium chloride is permitted in bread up to a maximum level of 2500 ppm of the flour.

Carrier or extraction solvents

Hexane is permitted as an extraction solvent for vegetable fats and oils with a maximum residue level of 10 ppm.

The *Regulations* also stipulate that food additives used in a product must be declared on the label of all foods (see Chapter 2). Provision is also made for the addition or deletion of compounds from the permitted list.

In these examples, it may be noted that in some instances finite limits of use have not been specified; instead, the term G.M.P. is used. This does not imply that the materials can be used in any amount. In fact, when the Tables state that such compounds may be used in accordance with "Good Manufacturing Practice" (G.M.P.), such limits are governed by *Regulation* B.01.044 as "the amount ... shall not exceed

the amount required to accomplish the purpose for which that additive is permitted to be added to that food."

Acceptance Procedure

Any manufacturer who wishes to use a new additive must present a submission to the Health Protection Branch according to the requirements stipulated in the *Regulations*. These requirements include:

- composition, properties, method of manufacture and specifications of the substance to be used as a food additive;
- amount and purpose of use;
- an acceptable method of analysis to determine presence and level of substance in food;
- data establishing that the food additive will have the intended physical or other technical effect;
- detailed reports of tests made to establish the safety of the food additive;
- a proposed maximum limit for residues of the food additive in or upon the finished food;
- specimens of the labelling proposed for the food additive;
- a sample of the food additive.

Policy on the Use of Food Additives

The following criteria form the basis of the Canadian policy in evaluating additives and are consistent with the recommendations of the FAO/WHO Joint Expert Committee on Food Additives:

- the food additive must be safe for continued use;
- its use must not lead to deception;
- its use must result in an advantage to the consumer by improving or maintaining the nutritive value, quantity, quality or acceptability of the food.

Even if a food additive is considered safe, its use will not be permitted if it may lead to deception, if it does not bring an advantage to the consumer or if it is not clearly established that it performs the function for which it is intended.

Safety Evaluation Procedure

Food additive submissions are evaluated by Health Protection Branch scientists in the Food Directorate, including toxicologists and food technologists. One of their major functions is to evaluate the safety of the proposed additive. The studies and data that are required for the evaluation of an additive include biochemical and physiological tests, subacute and chronic toxicity studies and reproduction studies.

From these investigations, a dosage that causes no demonstrable effect in the animals may be ascertained. Then the Acceptable Daily

Intake (ADI) for humans is calculated by dividing the "no-effect level" in the most sensitive animal species by a large safety factor, usually 100. Once the ADI is established, the Probable Daily Intake of this additive by the Canadian population is estimated. Comparison of the Probable Daily Intake with the ADI allows a rational decision to be made regarding the safety of a given additive for a proposed use.

Estimating the Probable Daily Intake of a food additive is an important part of the evaluation process. Accurate additive intake calculations require accurate food consumption estimates. Estimates of the consumption of a particular food commodity by Canadians in a given age group are often based on information provided by such domestic sources as the Nutrition Canada Survey. Depending on the techniques used to determine additive intake, estimates can be further supplemented by data obtained from other sources including industry-generated results, surveys carried out in other countries and domestic food consumption figures supplied by Statistics Canada. Such diverse sources of data help to ensure the accuracy of the intake estimates.

It should be noted that questions of toxicity are an international concern, and the Food and Agriculture Organization/World Health Organization Joint Expert Committee on Food Additives meets regularly to evaluate the toxicity of food additives. The recommendations of this expert committee are always taken into account in reviewing submissions presented by manufacturers.

Hypersensitivity to Food Additives

Just as certain individuals are hypersensitive to various food ingredients or even basic components of food, others may exhibit similar allergic-type responses or hypersensitivities to certain food additives. Such allergic reactions are unique to the individual; those affected must learn to avoid foods which can cause adverse responses. The requirement that ingredients and food additives be declared on the labels of prepackaged foods enables the consumer to recognize the presence of substances to which he or she has a known allergy or hypersensitivity. The diagnosis or treatment of a hypersensitive or allergy-prone individual is best left to a physician specializing in such matters.

Criteria for Purity

It is important that criteria for purity of food additives be defined to ensure that the quality of these chemicals is such that they can safely be used in foods. *Regulation* B.01.045 states that where specifications are set out in the *Food and Drugs Act and Regulations*, a food additive must meet those specifications. Where no specifications exist, the specifications set out in the *Food Chemicals Codex* must be followed. The *Food Chemicals Codex* is prepared by the Committee of Food Protection, the National Research Council and the National Academy of Science of the United States of America. Representatives from the

Health Protection Branch serve on committees that draft these specifications.

Food Colours

As one category of food additives, food colours are submitted to the controls outlined previously so their use does not constitute a danger to health and become a means to disguise a poor quality food.

The list of food colours permitted in Canada is more restrictive than in most countries. Besides natural colours, 10 synthetic colours are permitted. The *Regulations* provide for a fairly widespread use of eight of these while two others, Citrus Red No. 2 and Ponceau SX, are restricted respectively to the skins of whole oranges and to fruit peel, glacé fruits and maraschino cherries.

The other eight synthetic colours permitted for use are: Allura Red, Amaranth, Brilliant Blue FCF, Erythrosine, Fast Green FCF, Indigotine, Sunset Yellow FCF and Tartrazine.

Food Irradiation

The irradiation of food with gamma rays (or X-rays) is an effective technique for the preservation of food and is receiving renewed interest at the present time. In particular, irradiation of food can be used to:

- reduce pathogenic microorganisms of public health concern;
- reduce spoilage organisms thus extending shelf-life;
- prevent sprouting of vegetables;
- retard the onset of ripening of fruits;
- control insects in stored foods (as a replacement for chemical fumigants).

Gamma rays are a form of energy not unlike microwaves, infrared rays (heat energy) or visible light rays. Gamma rays have the ability to penetrate tissue producing small molecular changes which affect the viability of sensitive organisms such as bacteria, insects, etc. However, at irradiation dosage levels of practical importance in controlling such organisms, the effects on the food itself are minimal and not unlike the effects that result from other physical processes such as cooking, canning and freezing.

During the food irradiation process, the food is subjected to gamma rays originating from a radioactive element such as cobalt-60. However, it is important to recognize that the radioactive source never comes in contact with the food and no radioactivity is imparted to the food nor does the food become radioactive.

Over the years, extensive toxicity studies in laboratory animals have been carried out with many different foods. The results of these studies support the safety of foods treated by this process. In fact, the Food and Agriculture Organization/International Atomic Energy Agency/World Health Organization Joint Expert Committee on the Wholesomeness of

Irradiated Food recently concluded that foods irradiated up to an average absorbed dose of 10 kilogray (kGy) posed no hazard to consumers and that such foods were wholesome and not adversely affected in any way.

At present, in Canada, irradiation of food is regulated under the Food Additive Tables of the *Food and Drug Regulations*. Provision exists in Table VIII, Division 16 for the use of gamma irradiation on (1) potatoes and onions as an antisprouting agent, (2) wheat, flour and whole wheat flour for deinfestation purposes, and (3) whole or ground spices and dehydrated seasoning preparations to reduce the microbial load.

The Health Protection Branch has recently re-examined the existing regulatory mechanism for controlling food irradiation with a view to assessing its adequacy in terms of consumer protection and harmonization with international standards. As a result the Branch has proposed an amendment to the *Regulations* which would classify irradiation as a process and delineates pre-clearance requirements more appropriate to this process. An *Information Letter* on irradiation of food was released for public comment in 1983 and the Branch will respond to comments received through the issuance of a second *Information Letter*.

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Chapter 10

Flavours and Spices

Flavours and spices have been used for centuries to add sensory appeal to foods. Nevertheless, over time, a number of such products of both natural and synthetic origin have been found to be hazardous to health. Additionally, it has been found in certain cases that commercial products did not meet acceptable standards of purity and potency. Therefore, it was considered necessary to introduce a system of control.

Division 7 of the *Food and Drug Regulations* contains a number of regulations pertaining to spices. These regulations in the main define the botanical origin and essential composition of several important spices. The following is an example of one of these standards:

> B.07.023 (S). "Marjoram, whole or ground, shall be the dried leaves, with or without a small proportion of the flowering tops, of *Marjorana hortensis Moench* and shall contain
>
> (a) not more than
>
> (i) 10 per cent stems and foreign material of plant origin,
>
> (ii) 13.5 percent total ash,
>
> (iii) 4.5 per cent ash insoluble in hydrochloric acid, and
>
> (iv) 10 per cent moisture and
>
> (b) not less than 0.7 millilitres volatile oil per 100 grams of spice."

Division 10 of the *Food and Drug Regulations* contains several general definitions for types of flavours and, in addition, contains standards for flavouring materials important to the consumer. The goal of these standards is to guarantee a minimum potency and thus preclude fraud in this area. An example of a general definition and an example of a typical standard from Division 10 follow:

> B.10.004 (S). "Artificial (naming the flavour) Extract, Artificial (naming the flavour) Essence, Imitation (naming the flavour) Extract or Imitation (naming the flavour) Essence shall be a

flavouring extract or essence except that the flavouring principles shall be derived in whole, or in part, from sources other than the aromatic plant after which it is named, and if such extract or essence is defined in these *Regulations*, the flavouring strength of the artificial or imitation extract or essence shall be not less than that of the extract or essence."

B.10.019 (S). "Peppermint Essence, Peppermint Extract or Peppermint Flavour shall be the essence, extract or flavour prepared from peppermint or oil of peppermint, obtained from the leaves and flowering tops of *Mentha piperita* L., or of *Mentha arvensis* De C., var. piperascens Holmes, and shall correspond in flavouring strength to an alcoholic solution of not less than three per cent by volume of oil of peppermint, containing not less than 50 per cent free and combined menthol."

Of course, not all the spices known to man are listed in Division 7 of the *Regulations*, nor are all known flavouring materials listed in Division 10. Unlike the Food Additive Tables which are a "positive" list of those substances permitted to be used as food additives, flavours, spices and related substances which are considered to be unsafe appear on a "negative" list found in B.01.046 of the *Regulations* and are specifically prohibited. Any food found to contain substances on this negative list would be considered for regulatory purposes to be adulterated and thus subject to compliance action.

The emphasis of the Health Protection Branch's program in flavour evaluation is on less common natural flavour components and on synthetic flavour components not found in nature. Prior to acceding to the use of such substances in flavour preparations, the Branch may require toxicological information in order to assess their safety-in-use.

Several internationally recognized advisory lists of other flavouring substances are now available, the most notable being that of the Council of Europe. The *Food Chemicals Codex* (see Chapter 8) also contains chemical specifications for a number of flavouring materials. Finally, the FAO/WHO Joint Expert Committee on Food Additives has issued evaluations on several individual flavouring compounds over the years. The large body of international resource material assists Canadian regulators in evaluating specific flavour preparations and monitoring the use of flavours in the food supply to ensure that they do not pose a hazard to the human population.

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Chapter 11

Food-Packaging Materials

Food-packaging materials are an essential adjunct to modern food processing. They provide a variety of functions in addition to serving simply as containers for food products. For example, cans and specially constructed flexible pouches serve as vehicles in which food products are thermally processed to achieve commercial sterility. The milk pouch, boil-in-bag pouch and aseptic packages for milk and fruit juices are examples of packaging materials which were designed primarily with consumer convenience in mind.

Because of the many chemicals used in the manufacture of packaging materials and the potential migration of some of these chemicals to foods, it is necessary to control food-packaging materials to ensure that any packaging constituents which do migrate, pose no health risk to consumers.

As defined in the *Food and Drugs Act*, a "package includes anything in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed."

Therefore, in its broadest terms, a package may be regarded as any article which comes in contact with food during processing, distribution and sale. Based on this interpretation, a package includes such articles as tubing, holding tanks, conveyor belts and drums used in the food industry, and the many different types of containers in which foods are sold directly to the consumer.

Food-Packaging Material Regulations

Food-packaging materials and the components thereof are not considered to be food additives under the *Food and Drug Regulations*. Instead, they are specifically controlled under Division 23 of the *Regulations*.

B.23.001 states: "No person shall sell any food in a package that may yield to its contents any substance that may be injurious to the health of a consumer of the food."

Under this general prohibition, the food seller (i.e. the food processor, packager, distributor and retailer), bears the legal responsibility for the safety of the packaging material used.

As a consequence of the general nature of these *Regulations*, the Food Directorate of the Health Protection Branch receives, on a continuing basis, many submissions from packaging material manufacturers who supply the food industry requesting safety evaluations of their products. If, after evaluating the chemical composition of the material, its intended end use, the extractability of its constituents by foods and appropriate toxicological data addressing the safety of residues of those constituents in the food supply, the Branch is satisfied that the proposed use of the material is unlikely to pose a health hazard to consumers, a letter stating there is no objection to specified uses of the material is issued to the manufacturer.

The Health Protection Branch also provides advice to other government agencies on the interpretation of the *Regulations* pertaining to the safety of food-packaging materials. In this regard the Branch works closely with Agriculture Canada in particular, concerning materials used in food-processing establishments registered under the *Meat Inspection Act*.

In certain situations, specific regulations to protect consumers against potential health hazards from particular food-packaging materials are considered necessary. For example, *Regulation* B.23.003 permits the use of only two specific octyltin stabilizers in polyvinylchloride compounds used in the manufacture of food-packaging materials. This *Regulation* also sets limits on stabilizer use levels in the PVC compound and limits stabilizer migration to foods to 1 ppm. Other examples are: *Regulations* B.23.007 – to control residues of vinyl chloride in foods packaged in polyvinylchloride materials; and B.23.008 – to control acrylonitrile residues in foods resulting from the use of acrylonitrile-based plastic food containers.

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Chapter 12

Pesticides

Pesticides rank high on the list of technical innovations responsible for increased productivity in agriculture. Their use also parallels an improvement in the quality of agricultural products available on the Canadian market.

The Health Protection Branch works in close cooperation with Agriculture Canada and other agencies advising on the safe use of pesticide residues in food products offered to the consumer.

Before a pesticide product can be sold by a manufacturer for use on food crops or livestock or for use in areas where food may be handled or processed, the pesticide product must be registered by Agriculture Canada. This involves a review of the product by the Health Protection Branch and, if necessary, in the interest of the consumer, the conditions of use may be modified and a maximum residue limit established. Such a maximum residue limit is considered a safe level. The establishment of pesticide residue limits in or on food intended for human consumption was started in 1956, and today such limits are listed in Table II, Division 15, of the *Food and Drug Regulations*, for approximately 90 pesticides. The *Regulation* B.15.002 states:

(1) "Subject to subsections (2) and (3), a food is adulterated if an agricultural chemical or any of its derivatives is present therein or has been added thereto, singly or in combination, in an amount exceeding 0.1 part per million, unless it is listed in accordance with the (Food Additive) Tables to Division 16."

(2) A food is exempt from paragraph 4(d) of the *Act* (no person shall sell any article of food that is adulterated) if the only agricultural chemicals that are present therein or have been added thereto are any of the following:

(a) a fertilizer
(b) an adjuvant or a carrier of an agricultural chemical
(c) an inorganic bromide salt
(d) silicon dioxide
(e) sulphur or
(f) viable spores of *Bacillus thuringiensis Berliner*.

(3) A food named (in Table II) is exempt from paragraph 4(d) of the *Act* if the agricultural chemicals named are present therein or have been added thereto in an amount not exceeding the limit, expressed in parts per million for that food.

Procedure to Determine Pesticide Maximum Residue Limits

The Health Protection Branch requires manufacturers of pesticides for which maximum residue limits on foods are to be established to submit detailed data on the following:

- specifications and composition of the substance to be used as a pesticide;
- the physical and chemical properties of the substance;
- plant and animal metabolism studies;
- evidence that the product is effective and practical;
- the amount to be applied, frequency and time of application;
- satisfactory method of analysis for determining residues in foods;
- studies designed to determine residue levels on each food;
- toxicity studies;
- proposed maximum residue limits for each food.

Assessment of Acceptable Daily Intake

As discussed previously in conjunction with food additive evaluations, the Acceptable Daily Intake (ADI) for man is usually determined on the basis of the data obtained in toxicity studies done on mammals. The starting point chosen is the dose level that causes no observable effect in the most sensitive species.

This dose in mammals, expressed in mg/kg of body weight, is divided by a large safety factor, usually 100. The value thus obtained is considered to be the Acceptable Daily Intake, i.e. the maximum daily dose of the chemical that is considered to be without appreciable risk when taken by man throughout his entire lifetime.

Residue Limits in Foods

Maximum residue limits (MRLs) are established to cover residues remaining in food at point of sale (e.g. harvest of crops, slaughter of animals).

It is the policy of the Health Protection Branch to establish such MRLs providing they are consistent with good agricultural practices and are considered to be safe.

A calculation of the maximum daily intake is made based on the MRLs proposed and on estimates of consumption of the foodstuffs concerned. Possible intake of residues from other sources (e.g. previously approved uses where MRLs have been established) is also accounted for in this calculation. Providing the estimated daily intake does not exceed the Acceptable Daily Intake estimated from toxicity studies, MRLs are accepted. Some examples of pesticide MRLs in parts per million (ppm) allowed in or on foods as listed in Table II, Division 15, are as follows:

Table 15: Maximum Residue Limit

Chemical	*Parts per million*	*Foods*
Captan	5	Apples, apricots, blueberries cranberries, cherries, grapes, peaches, pears, plums, raspberries, strawberries, tomatoes
Methomyl	5	Cabbages
	4	Grapes
	2	Lettuce
	1	Citrus fruits
	.5	Apples, celery
Metribuzin	.5	Potatoes
Thiabendazole	10	Apples, citrus fruit, pears
	4	Potatoes
	.4	Bananas (edible pulp)

Pesticide residue limits and the use of pesticides are constantly being reviewed and revised in the light of new data regarding toxicity and through new methods of analysis for detection of residues. The Branch participates in a number of ongoing committees (e.g. the Canadian Association of Pesticide Officials) that deal with pesticide issues and include representatives from federal as well as provincial agencies involved in the pesticide review and control process.

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Chapter 13

Veterinary Drug Residues in Foods

Veterinary drugs of all types play an essential role in modern animal husbandry. Without the use of drugs to combat infection, prevent disease, control parasitism and promote growth, modern livestock production would not be possible and our food would be more expensive and less plentiful.

Regulations

The control and regulation of all veterinary drugs is the responsibility of the Bureau of the Veterinary Drugs of the Health Protection Branch, and is legislated under the *Food and Drugs Act and Regulations*.

Veterinary drugs are classed either as prescription drugs which can be obtained only by prescription from a licensed veterinarian or as non-prescription drugs which may be legally purchased by the public "over the counter". The conditions for the sale of a veterinary drug for use in animals, birds or fish are specified in Part C of the *Food and Drug Regulations*. In addition, animal feeds that contain veterinary drugs are regulated under the *Feeds Act and Regulations* administered by Agriculture Canada. A prescription from a licensed veterinarian is necessary when the level of a drug in a feed or the conditions of use of the medicated feed differ from those specified on the drug label.

Unlike drugs for human use, veterinary drugs must be carefully assessed for their potential to leave drug residues in edible tissues, milk and eggs and are regulated accordingly. For example, *Regulation* C.01.606 prohibits the sale of antibiotic preparations for the treatment of cattle unless where

(a) the preparation is not to be used for lactating cattle and the inner and outer labels carry a statement to that effect, or

(b) the preparation may be used for lactating cattle,

(i) there has been submitted, on request, to the Director, acceptable evidence to show the period of time that must elapse after the last treatment in order that the milk from treated lactating animals will contain no residues of antibiotics, and that period does not exceed 96 hours;

(ii) the main panel of the outer label and either the inner label or a packaging insert describing the antibiotic preparation carries the words "Warning: milk taken from treated animals within ... hours after the latest treatment must not be used in food"; and

(iii) the blank on this label is filled in with a figure determined in accordance with this paragraph.

As another example, C.01.610 prohibits the sale of any substance having estrogenic activity for administration to poultry that may be consumed as food.

Comprehensive studies are required from the manufacturer and the data generated are scrutinized by Health Protection Branch experts to assess the safety of a veterinary drug for humans. The metabolism and toxicity of veterinary drugs are initially studied in laboratory animals. Such hazards as carcinogenicity, teratogenicity, mutagenicity and reproductive effects are all carefully assessed for possible effects in humans through the ingestion of residues in food. The residues of veterinary drugs or metabolites are measured by reliable analytical methods to determine the rate of depletion from the tissues of the treated food-producing animal or bird. Maximum permissible levels in food for each drug are calculated from the data supplied, and this, together with the residue depletion data, is used to calculate the withholding time. To ensure the safety of certain drugs, Branch experts assign withdrawal periods which define the minimal period of time between the last recommended treatment and the time of slaughter or, in the case of milk and eggs, collection for use as food. The withholding time and factors such as species, sex, frequency of use, age, route of administration, and other strict conditions for the use of the drug are prescribed on the accompanying label. If a drug is found to require a long or impractical period of time to deplete from animal tissues, milk or eggs or is found to be a potential carcinogen or teratogen, its sale for use in food-producing animals or birds in Canada is not permitted.

Monitoring of Veterinary Drug Residues in Food

Residues of veterinary drugs in food are monitored selectively by a number of federal and provincial agencies. Health Protection Branch scientists in the Bureau of Drug Research develop and perfect analytical methods that enable the effective field testing of food products by both the Field Operations Directorate and Agriculture Canada laboratories. Analysis of animal tissues (meat, liver and kidneys) and of milk and eggs

is done according to sampling programs. In some cases, violations may be suspected in the abattoir, before meat is marketed, when there is evidence of injection sites. Such evidence initiates testing for residues, and offenders are investigated under the *Food and Drugs Act and Regulations*.

In the case of milk, provincial authorities and dairies routinely conduct antibiotic residue testing before bulk milk is assigned for human consumption or for processing into cheese, butter or other dairy products. If raw milk is found to contain unacceptable levels of drug residues, severe financial penalties or loss of milk quotas to the producer can result.

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Chapter 14

Health Protection Branch

Of the five program directorates in the Health Protection Branch, two have major roles in identifying and controlling hazards in foods. The Food Directorate and the Field Operations Directorate work together to ensure that the Canadian food supply is nutritious and has a high standard of safety and quality. Basically the Food Directorate is involved in research, evaluation and the development of food standards and regulations while the Field Operations Directorate handles the inspection and compliance activities. The Drugs Directorate is also involved but to a minor extent in terms of veterinary drug residues in foods as was discussed in Chapter 13.

Food Directorate

The Food Directorate is responsible for program policies and priorities in all areas of food safety and nutritional value. General activities include:

- applied and fundamental research in the food area;
- assessment of monitoring and surveillance data generated by the Field Operations Directorate in the development of standards and regulations;
- development of standards, regulations and guidelines;
- development and standardization of analytical methods for use in regional laboratories.

It has three bureaus: chemical safety, nutritional sciences and microbiological hazards.

Bureau of Chemical Safety

This Bureau is responsible for research, evaluation and standard-setting activities involving agricultural chemicals, food additives, food-packaging materials and chemical contaminants in the food supply. It is involved in the identification and assessment of hazards related to chemicals in foods, particularly assessment of human intake and tolerance.

Research entails the development of analytical methods including more sensitive methods to determine, for example:

- trace elements (e.g. lead, cadmium in foods);
- mycotoxins (e.g. vomitoxin in grains and grain products);
- chlorinated hydrocarbons (e.g. dioxins and furans in fish).

It also includes the study of toxic effects of:

- trace elements (e.g. the effects of low lead levels on learning behavior in monkeys);
- chlorinated hydrocarbons (e.g. the long-term effects of PCBs in the diet of monkeys);
- mycotoxins (e.g. the long-term effects of vomitoxin in the diet of mice).

Evaluation may entail:

- the estimation of the daily intake of food chemical contaminants (e.g. vomitoxin in the human diet);
- the determination of the significance of levels of food chemical contaminants in the human diet (e.g. lead in canned foods);
- the recommendation of regulatory and other control measures to prevent potentially harmful exposure of the consumer to food chemical contaminants (e.g. guidelines for mercury and PCBs).

In terms of pesticides, for example, evaluation of pesticide residues in an average meal as consumed by Canadian families (total diet studies) indicate that the present amounts of pesticide residues are far below the Acceptable Daily Intake for all pesticides.

The Bureau recommends regulatory and non-regulatory controls relating to the safety of food chemical contaminants and chemicals used in the manufacturing, processing and distribution of food products.

Bureau of Nutritional Sciences

This Bureau is responsible for programs relating to the composition and nutritional quality of the food supply.

Activities include:

- development of food standards regulations (e.g. food fortification programs to correct diet deficiencies and food enrichment;
- evaluation of technical and scientific information contained in submissions (e.g. food composition, food ingredients, new food products);
- development of analytical methods;
- collection and assessment of information on the nutritional status of Canadians;

- provision of advice on nutrition to other government agencies, educational organizations, the food industry and consumer.

Bureau of Microbial Hazards

This Bureau is responsible for research, evaluation and standard-setting activities with respect to microbial hazards and extraneous material in the food supply. Activities include:

- development of methods for detecting microorganisms, toxins and extraneous material in foods;
- identification of various infectious and toxigenic microorganisms associated with cases of food poisoning;
- recommendation of measures towards the prevention of conditions leading to microbial growth and toxin production;
- evaluation of the significance of microbial contaminants;
- establishment of national standards and guidelines for the microbiological safety and hygiene of foods offered for sale in Canada.

Field Operations Directorate

The Field Operations Directorate promotes industry compliance with the *Food and Drugs Act and Regulations* and other applicable standards, guidelines and codes of practice. In addition to a headquarters operation in Ottawa, the Directorate has a field organization in five regions across the country. Each region has a central office with laboratories plus additional district offices located strategically throughout the region.

The regional and district offices are:

Atlantic Region: Ralston Building, 1557 Hollis Street, Halifax, Nova Scotia B3J 1V5. Telephone (902) 426-2160.
Districts: St. John's (709) 772-5536; Saint John (506) 648-4860; Charlottetown (902) 566-7871; Halifax (902) 426-5773.

Québec Region: 1001 St. Laurent Street W., Longueuil, Québec J4K 1C7. Telephone (514) 283-5488.
Districts: Québec (418) 648-3670; Sherbrooke (819) 565-4916; Trois-Rivières (819) 374-6259; Hull (819) 997-3035; Montreal East (514) 283-5473; Montreal West (514) 283-5484.

Ontario Region: 2301 Midland Avenue, Scarborough, Ontario M1P 4R7. Telephone (416) 973-1600.
Districts: Hamilton (416) 572-2568; London (519) 679-4125; Thunder Bay (807) 344-6521; Sudbury (705) 675-0606; Ottawa (613) 954-6807; Toronto East (416) 973-1436; Toronto Central (416) 973-1586; Toronto West (416) 973-1591.

Central Region: 310 Federal Building, 269 Main Street, Winnipeg, Manitoba R3C 1B2. Telephone (204) 949-5490.
Districts: Brandon (204) 727-6577; Regina (306) 780-5407; Saskatoon (306) 975-4502.

Western Region: 3155 Willingdon Green, Burnaby, British Columbia V5G 4T2. Telephone (604) 666-3359.
Districts: Victoria (604) 388-3166; Kelowna (604) 763-9441; Edmonton (403) 420-2626; Calgary (403) 292-4650; Vancouver (604) 666-3844.

Inspection

Each inspection division consists of an operational staff trained at the professional and technical levels in scientific areas such as microbiology, chemistry and food science; the inspectors travel from the Regional or District offices to deal with industry and consumers.

Field Operations inspectors may gather data to provide support to the Food Directorate such as monitoring the levels of trace elements in food (e.g. lead in canned food) or to provide a service to other agencies. During inspections of food manufacturers or of import shipments, inspectors collect product samples. Examination of food samples is conducted at the regional laboratories to determine if a product is in compliance with the *Regulations* (e.g. aflatoxin levels in peanut butter or excessive residues of pesticides).

Inspectors also collect field intelligence information from other government agencies, private institutions and other sources, and conduct investigations into problems identified by consumers, other Branch Directorates and other Canadian and international government agencies.

Compliance

Most of the industry is willing to comply with food and drug legislation and the Health Protection Branch works towards voluntary compliance. However, there are occasions when products are not in compliance and/or present a health hazard. In these situations, the Field Operations Directorate monitors product recalls, detains products, and holds interviews at which time individuals who have violated provisions of the *Act* are given the opportunity to outline what corrective action they are prepared to undertake.

Inspectors enforce the *Food and Drugs Act* by seizing violative products, recommending to the Collector of Customs the refusal of entry into Canada of violative imports, or by initiating prosecution actions in court.

Education

Constant contact is maintained with the food industry; workshops are held with manufacturers in various regions to promote good manufacturing practice, and seminars are conducted with food import-

ers. Inspectors provide advice on the improvement of sanitary conditions, as needed.

In addition, Educational Services Consultants within the Field Operations Directorate have made food safety a major program with health professionals, educators and the media. Resource materials designed to acquaint food handlers and consumers with the importance of good food-handling practices are available through the regional offices.

Halifax: Health Protection Branch, Ralston Building, 1557 Hollis Street, Halifax, Nova Scotia B3J 1V5. Telephone (902) 426-2160.

Québec: Health Protection Branch, 1001 rue St. Laurent ouest, Longueuil, Québec J4K 1C7. Telephone (514) 283-5488.

Ontario: Health Protection Branch, 2301 Midland Avenue, Scarborough, Ontario M1P 4R7. Telephone (416) 973-1600.

Manitoba and Saskatchewan: Health Protection Branch, 310-269 Main Street, Winnipeg, Manitoba R3C 1B2. Telephone (204) 949-5490.

British Columbia and Yukon: Health Protection Branch, 3155 Willingdon Green, Burnaby, British Columbia V5G 4T2. Telephone (604) 666-3359

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Material available from the Field Operations Directorate, Health Protection Branch:

Protection is Our Middle Name (folder).

How to Lodge a Complaint Effectively (folder).

Canada

Lumberjacks' Breakfast
by W. Kurelek
Collection of the Art Gallery of Greater Victoria
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